

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Solicits Public Comments on Cloned Animal Assessment and Guidance

“The draft risk assessment finds that meat and milk from clones of adult cattle, pigs and goats, and their offspring, are as safe to eat as food from conventionally bred animals,” according to an FDA press release announcing [draft documents](#) on the safety of animal clones. In addition to the risk assessment, FDA has issued a proposed risk management plan to address “potential remaining uncertainties” as well as draft guidance for industry. The guidance does not make special recommendations for “human food use” of clones, but expects that most clones will be used as “elite breeding stock.” Comments on the draft documents should be submitted to FDA by April 3, 2007. *See FDA Press Release*, December 28, 2006; *Federal Register*, January 3, 2007.

While scientists and agriculturists consider the FDA assessment, consumer groups have already criticized it as flawed. “FDA is essentially giving a couple of cloning companies a Christmas present at the expense of consumers and the dairy industry,” a Center for Food Safety spokesperson told the

press. Other critics have derided cloned animals as allegedly reinforcing genetic abnormalities when selected for optimum milk or meat production. Meanwhile, farmers are reportedly deciding whether the benefits of cloned breeding stock outweigh public distrust. *See Center for Science in the Public Interest Press Release*, December 28, 2006; *Reuters*, December 29, 2006; *Food Navigator USA.com*, January 3, 2007.

U.S. Department of Agriculture (USDA)

[2] CSPI Files Petition to Limit Salt in Meat and Poultry Products

The Center for Science in the Public Interest (CSPI) has filed a [petition](#) under the Administrative Procedure Act asking the USDA’s Food Safety and Inspection Service (FSIS) “to establish ceilings for sodium in various categories of products containing meat or poultry.”

According to the petition, meat and poultry products such as ham, sausage, hot dogs, sliced turkey breast, and chicken nuggets, which vary widely in their sodium content, are responsible for some 11 percent of Americans’ total sodium intake. CSPI contends that such variations “clearly demonstrate that – without affecting the safety of the food – it is feasible for the firms making high-sodium products to lower sodium levels and still have tasty products that would be competitive in the marketplace.”



CSPI refers to its November 2005 petition, which asks the Food and Drug Administration (FDA) to revoke its “generally recognized as safe” (GRAS) classification for salt, and suggests that USDA not wait for the FDA to act. The petition calls for FSIS to “immediately announce that it will propose regulations that would set ceilings for sodium in various categories of products containing meat or poultry. Those ceilings might be set equal to the average or median level of sodium in different brands of the same food, the lowest level found in any brand with significant sales, or some other standard.” According to CSPI, the average per capita sodium consumption in the United States is “well above” the FDA’s current recommended level.

2006 Regulatory Review

[3] Food Marketing and Childhood Obesity

Throughout 2006, lawmakers and federal agencies addressed food marketing and its purported effect on childhood obesity. Efforts by the 109th Congress to increase government oversight included a House bill (H.R. 5737) that proposed authorizing the Federal Trade Commission (FTC) to curb food and beverage marketing geared toward children younger than age 18. In September, the U.S. Senate approved the Children and Media Research Advancement Act (CAMRA), directing the Centers for Disease Control and Prevention (CDC) to study the impact of electronic media on child development and to report its findings to Congress.

In a joint report with the Department of Health and Human Services, the FTC also recommended that food companies revise their marketing practices to help consumers make nutritious choices. In May, several state attorneys generals pressed the FTC to

restrict alcohol advertising to media that obtains only 15 percent of its audience from the 12-to-20 age bracket. Later the FTC proposed a “compulsory process order” to gather data from alcohol advertisers on their compliance with voluntary industry guidelines. A second FTC notice, distributed to food and beverage companies, solicited information on kid-oriented marketing for a media report requested by Congress. In a December letter to consumer groups, however, the commission explained that it was not going to regulate “word-of-mouth” marketing.

The Federal Communications Commission (FCC) announced its own task force on advertising and children’s health in 2006. Including industry representative and public advocates, the task force reportedly aims to “encourage best practices for industry and continue to educate American parents.” The FCC also issued a final rule on children’s programming guidelines, effective January 2, 2007, amending host selling restrictions for Web sites. Host selling restrictions prohibit TV characters from selling products during or adjacent to the shows in which they appear. The guidelines further revised the definition of “commercial matter” and vacated “the percentage cap on the number of permissible core program preemptions.”

In international developments, the World Health Organization (WHO) in November unveiled an anti-obesity charter that claims to protect “vulnerable groups such as children and adolescents, whose credulity should not be exploited by commercial activities.” Signed by European health ministers, the charter also “calls for specific regulatory measures” beyond industry self-regulation. An independent media regulator in the United Kingdom followed suit with a ban on advertising foods high in fat, salt or sugar to children younger than 16.



[4] Food Safety

In a year characterized by reports of foodborne illnesses and escalating rates of obesity, this Report covered numerous regulatory measures enacted by the Food and Drug Administration (FDA) and the Department of Agriculture (USDA). Among the guidance issued in 2006, FDA (i) defined “whole grains” as containing the same proportions of primary components as intact grain; (ii) proposed a rule to disclose cochineal extract and carmine, insect-derived additives, on food labels; (iii) revised food allergen labeling guidelines; (iv) announced voluntary food retail standards aimed at creating national uniformity among regulators; and (v) set lead limits of 0.1 ppm in candy consumed frequently by children. FDA also held public hearings on whether “functional foods” making health claims beyond basic nutrition should be more closely regulated.

USDA began the year with an audit faulting the Grain Inspection, Packers and Stockyards Administration for allegedly shortchanging laws meant to prohibit unfair, deceptive and fraudulent practices. The agency also recommended changes to a Food Safety and Inspection Service (FSIS) review system after FSIS failed to ensure that state meat and poultry inspection programs met federal standards. In December, the agriculture department announced that the controversial National Animal Identification System (NAID), designed to track livestock disease outbreaks, would remain voluntary. Other key issues for USDA in 2006 included (i) an interim final rule on sodium content and “healthy” labeling; (ii) a recall proposal that would allow FSIS to publicly list retail consignees of voluntarily recalled meat and poultry products; (iii) an interim final rule requiring mandatory country-of-origin labeling for fish and shellfish; and (iv) proposed organic certification for farm-raised fish.

Several foodborne illness outbreaks were linked to raw produce in 2006, the most significant involving spinach processed by Natural Selection Foods LLC that reportedly sickened 200 people. In an effort to improve industry practices and recall procedures, FDA extended its Lettuce Safety Initiative to all raw produce. This *E. coli* outbreak also revived the Safe Food Act of 2005, which called for a centralized food safety system and a coding system to facilitate disease investigation. Although the bill did not become law, its precepts were echoed in major newspapers and food magazines at the end of the year. “Aside from undue corporate influence and inadequate funding, America’s food-safety system is hampered by overlapping bureaucracies,” Eric Schlosser opined in a *New York Times* piece supporting a renewal of the Act in the 110th Congress.

[5] State/Local Initiatives

As part of the nation’s continuing focus on obesity, several state and local governments responded to public pressure for new health initiatives. In May, Connecticut prohibited the sale of soft drinks, sports drinks and juices that contain less than 100 percent fruit juice in middle, elementary and high schools. That same month, three major soft drink manufacturers pledged to stop selling non-diet beverages in schools by 2009, a plan confirmed by the release of the School Beverage Guidelines in September. Promoted by the American Beverage Association, the guidelines will provide “lower-calorie, nutritious, smaller-portion beverage choices” to students. Other states considering similar school nutrition laws, such as Illinois and Colorado, elected not to ban “junk food” or establish dietary guidelines, partly because the proposals apparently failed to offer a comprehensive solution to children’s sedentary lifestyle.



The New York City Board of Health took unprecedented action in demanding that all city restaurants phase out *trans* fat from frying oils and menu items over the next 18 months. The city further requires that any restaurant disclosing nutritional information to the public must also list calorie content on menus and menu boards. Although many restaurants have already eliminated *trans* fat, both Chicago and Washington state are reportedly considering similar bans.

[6] GM Issues

Genetically modified (GM) crops continued to feed global debate in 2006 as many countries took sides on the issue. In the United States, Representative Dennis Kucinich (D-Ohio) introduced several bills that would have increased company liability for GM organisms, mandated labeling for GM foods and placed limits on GM exports. None of the bills became law.

In May, Poland approved a national ban on the sale and registry of GM seeds, a move that risked conflict with European Union (EU) laws against instituting blanket bans without scientific evidence. Later the World Trade Organization ruled in the United States' favor on GM crops, stating that the EU had imposed an illegal moratorium on approving GM products from 1999 to 2003.

Litigation

[7] Kraft's Capri Sun® Products Challenged for "All Natural" Label

A Florida woman has filed a putative class action in state court seeking a declaration that marketing fruit-juice products containing high fructose corn syrup (HFCS) as "all natural" is unfair and deceptive.

Linda Rex is also asking the court to require manufacturer Kraft Foods, Inc. to disgorge profits from such alleged deception. Her suit is filed on behalf of "all consumers who purchased Capri Sun products in the State of Florida beginning four years before the date the Complaint is filed until the date of class certification." [*Linda Rex v. Kraft Foods, Inc. \(Palm Beach County, Florida, filed Jan. 8, 2007\)*](#).

The Center for Science in the Public Interest (CSPI) is assisting the plaintiff who contends that "the molecules in HFCS (and Capri Sun) were not extracted from natural sources, but created through enzymatically catalyzed chemical reactions in factories." That process is more fully detailed in the complaint, which includes counts for violation of Florida's Deceptive and Unfair Trade Practices Act, unjust enrichment and breach of express warranty.

According to a news source, one issue complicating the matter is that the Food and Drug Administration (FDA) has never defined "natural." The U.S. Department of Agriculture states that products can be labeled "natural" if they contain no artificial or synthetic ingredients and are minimally processed. The FDA has been petitioned to adopt this definition; its current policy merely states that foods are "natural" when "nothing artificial or synthetic" has been added that would not normally be expected. CSPI Executive Director Michael Jacobson was quoted as saying, "high fructose corn syrup isn't something you could cook up from a bushel of corn in your kitchen, unless you happen to be equipped with centrifuges, hydroclones, ion-exchange columns, and buckets of enzymes." A Kraft spokesperson reportedly said the company has been working on reformulating its Capri Sun® beverages for a year and will soon be marketing the products not as "all natural," but as



containing no artificial colors, flavors or preservatives, which apparently “resonated well with consumers.”

CSPI threatened Cadbury Schweppes in 2006 with similar litigation regarding its 7UP® products and has been in negotiations with the company. If a settlement cannot be reached, CSPI has promised to sue that company as well.

2006 Litigation Review

Among the dozens of cases we reported in 2006, those bringing deceptive marketing claims predominated. From the lactose intolerant to those alleging aggravation of the symptoms of autism, none actually succeeded in 2006 in holding an industry defendant liable for personal or economic injury. This has not, however, stopped the plaintiffs’ bar and public health advocates from threatening to sue or filing suit in state and federal courts across the country. And while they recognize the obstacles they face linking obesity-related disease endpoints to the consumption of a specific product or defendant, there is no indication that they will abandon the courtroom anytime soon in their efforts to address the so-called obesity epidemic. This overview also includes those cases, not obesity-related, that could otherwise have an impact on diverse sectors of the food and beverage industries.

[8] Litigation Threats

The Center for Science in the Public Interest (CSPI) had another busy year as it informed soft drink manufacturers, food companies and even a cable TV station that it was poised to file lawsuits against them. Among CSPI’s demands was that companies (i) cease advertising “nutritionally poor products” on TV to children younger than age 8, (ii) refrain from calling a product “natural” when it

contains high fructose corn syrup, (iii) remove sweetened beverages from school vending machines, and (iv) more prominently display information about the fat substitute Olestra® on product packaging. CSPI actually filed suit against one fast-food company, claiming that it deceptively advertised its products by failing to warn consumers about its use of *trans* fats. That suit was dropped when the company announced it would be switching to other types of shortening in its food-preparation processes. Former anti-tobacco activist John Banzhaf took the issue of school pouring contracts to a new level by informing school boards and individual school board members across the nation that they could be held personally liable for injury allegedly caused by the foods and drinks sold in school vending machines.

[9] Youth Marketing

Pelman v. McDonald’s Corp. The case that launched the food litigation trend came closer to trial in a New York federal courtroom with the judge ordering McDonald’s to respond to the plaintiffs’ second amended complaint. The litigation involves claims by overweight minors who allege injury from consuming the company’s fare. Their claims for deceptive advertising will be limited to specific advertisements, which they contend, caused them to consume fast food and led to their obesity and adverse health effects. The public health community is keenly interested in the case and is hoping that documents produced during pre-trial discovery will place the defendant in a bad light and bolster their crusade. The case has been discussed in a number of legal articles and has even been added to a case book for foreign and pre-law students titled *An Introduction to the United States Legal System: Cases and Comments*.



Cases with a youth marketing component filed in state and federal courts against the alcohol industry were uniformly unsuccessful in 2006. Courts in Ohio, Wisconsin, the District of Columbia, and West Virginia unanimously rejected claims that advertisements deliberately directed at youth were responsible for a misuse of family funds because they were causing underage consumers to buy alcoholic beverages. Dismissing such suits, the courts found that the plaintiffs had either stated no cause of action or lacked standing, or that the illegal act of minors buying alcohol broke the chain of causation necessary to sustain a claim of injury.

[10] Deceptive Advertising/Trade Practices

Claims of this nature were at issue in cases involving products ranging from McDonald's french fries to a Chicago producer's hot dogs. When McDonald's announced that its fries were prepared with wheat and dairy ingredients, numerous class action lawsuits were filed in courts across the nation by vegans and the gluten-intolerant. The Judicial Panel on Multidistrict Litigation has consolidated the federal suits, and pre-trial activities are now in the hands of a judge in the Northern District of Illinois. Litigants in California contend that the gluten and casein in McDonald's fries aggravated their child's autism.

Individuals who claim to be "observant" Jews filed a putative class action against a hot dog producer in Chicago that advertises its products as 100 percent beef. According to the plaintiffs, such claims constitute a breach of express warranty and consumer fraud, because the company uses pork intestines as casings. And in California, a woman who has filed a number of product-related cases sued Kraft Foods Inc., alleging that its guacamole dip is mislabeled because avocado is among the least of its ingredients.

We also reported in 2006 that a California appeals court dismissed deceptive trade practice claims filed against grocery store owners and operators for selling farm-raised salmon without disclosing that they are fed chemicals to turn their flesh pink like that of wild salmon. In December 2006, the California Supreme Court agreed to hear an appeal from that decision. A federal court in Virginia dismissed consumer fraud claims filed against dairy producers and marketing groups that promoted the consumption of dairy products as a healthy way to lose weight. According to the court, state law did not make such relief available to private litigants.

[11] Proposition 65 Product Warnings

California's Prop. 65, which requires warnings to consumers about the presence of substances known to the state to cause cancer or constitute reproductive toxicants, provided a fertile ground for food plaintiffs. We reported that Pepsico responded to a Prop. 65 suit by agreeing to phase out the use of soft drink bottles from Mexico whose labels contained lead in the ink, while Mexican subsidiaries of U.S. candy manufacturers agreed to adopt processes that eliminate lead from their candies and packaging materials. Suit was also filed under Prop. 65 against Burger King for failing to warn that its grilled burgers contain polycyclic aromatic hydrocarbons (PAHs). In cases filed against fast-food companies for not warning about acrylamide in their products, a trial court lifted a stay that had been entered to allow a state agency to adopt acrylamide regulations. The agency failed to do so within the one-year deadline that had been imposed.

In other Prop. 65 litigation, a court ruled that the state cannot require tuna manufacturers to warn that their products contain mercury and mercury compounds. The court reasoned that such action is



preempted by federal law, the low levels of mercury do not merit warnings, and mercury occurs naturally in fish. We also reported that a federal court in California dismissed claims that ConAgra Foods, Inc. misled consumers by failing to warn that microwave popcorn bags contain a carcinogenic chemical that is absorbed by the popcorn while the product cooks.

Also dismissed were claims filed in federal court by individuals who allege they are lactose intolerant. They were seeking product labels about the risks of lactose intolerance. The court determined that such claims are preempted by federal law.

[12] Bovine Spongiform Encephalopathy

Three cases involving BSE were reported in 2006. A Kansas meat processor that wants to test its cattle for BSE is litigating the issue against the U.S. Department of Agriculture which apparently controls the use of the test kits under a federal law relating to swine. Dispositive motions are pending. Ranchers and cattlemen, known by the acronym R-CALF USA, are also litigating BSE issues against USDA. They seek restrictions on cattle imports. In 2006, the Ninth Circuit Court of Appeals denied the government's motion to dismiss the appeal, and briefing was scheduled to conclude in February 2007. North of the border, Canadian farmers are suing their government for not timely acting to ban the use of ruminant meat and bone meal in cattle feed.

[13] Genetically Modified Organisms

Genetically modified crops were at issue in a number of lawsuits. In good news for the GMO industry, the World Trade Organization ruled that there was no scientific basis for the European Union's restrictions on the import of biotech crops and foods. A federal court in Hawaii, however, ruled that the USDA violated environmental law

when it issued permits to allow the cultivation of biopharmaceutical crops without undertaking environmental studies. Rice farmers in the United States have filed several class action suits against Bayer CropScience claiming that the company's genetically engineered crops contaminated their crops which lost value in international markets due to the contamination. Some countries also suspended long-grain rice imports altogether. These suits were consolidated by the Judicial Panel on Multidistrict Litigation in December 2006 and assigned to a federal judge in the Eastern District of Missouri. Also pending is a suit filed against the Food and Drug Administration by a group seeking a response to the rulemaking petition it filed with the agency seeking controls on genetically engineered foods.

[14] Foie Gras

Animal rights groups convinced Chicago's City Council to prohibit foie gras sales in city restaurants, and restaurateurs fought back by filing a suit challenging the council's action as unconstitutional. They claim the council's powers are limited to local concerns; because no foie gras is produced locally, they contend that the city council acted in excess of its powers. The Humane Society has filed suit against the New York State Department of Agriculture seeking a ban on the production and sale of foie gras. If this suit succeeds, foie gras will apparently no longer be produced in the United States because the only producers are located in New York.

[15] *E. Coli*

Following an *E. coli* outbreak that killed three and sickened several hundred, personal injury lawsuits were filed in a number of states against a California company that grows and ships bagged



fresh spinach nationwide. Federal researchers apparently traced the *E. coli* strain implicated in the outbreak to animals living near the company's fields. An Illinois restaurateur also filed a putative class action lawsuit against the company seeking to recover the cost of spinach that had to be discarded. In December 2006, the parents of a 9-year-old girl who was hospitalized for kidney complications related to *E. coli* after eating at a Taco John's in Iowa filed a lawsuit against the restaurant chain in federal court.

[16] Salt

While CSPI continues its campaign to reduce salt levels in prepared foods by writing warning letters to food producers and restaurateurs, the Salt Institute and the U.S. Chamber of Commerce were unsuccessful in their suit which challenged the quality of the data behind the findings of the National Heart, Lung and Blood Institute which suggest that Americans can lower their blood pressure by reducing salt consumption. The Fourth Circuit Court of Appeals dismissed the claims, ruling that the federal Information Quality Act does not allow such actions.

[17] Miscellany

When reports of benzene in soft drinks hit the news, lawsuits were filed in Florida, Massachusetts and Washington. We learned that the latter case was

settled after the producers agreed to change product ingredients to reduce the likelihood of benzene forming due to a chemical reaction at increased temperatures. Two lawsuits were filed in California over the classification of flavored malt beverages. In one suit, a county sought a change in the classification for taxing purposes; in the other, advocacy groups sued the Department of Alcoholic Beverage Control to change the classification from beer to distilled spirits. An appeals court turned aside the latter suit. The Fourth Circuit Court of Appeals issued a split decision that upheld Virginia's Alcohol Beverage Control Act in the face of challenges by out-of-state wineries which claimed that the three-tier distribution system violated the dormant Commerce Clause. We also reported that the Eight Circuit Court of Appeals ruled that Nebraska's constitutional ban on corporate farming violated the U.S. Constitution. The final case we reported in 2006 was a ruling by a federal court in New York dismissing claims filed by a Florida man against the company responsible for the Atkins diet. He alleged that the defendant's books and food products caused his heart disease, but the court found it was common knowledge that foods high in cholesterol consumed in quantity could cause adverse health effects.



Food & Beverage

LITIGATION UPDATE

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