Food & Beverage

LITIGATION UPDATE

Issue 209 • April 5, 2007

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Publishes Proposed Rule on Irradiated Food Labeling

FDA has published a proposed **rule** that would require foods materially changed by irradiation to be labeled with a logo and the term "irradiated," along with "explicit language describing the change in the food or its conditions of use." Written comments on the rule must be submitted by July 3, 2007, while comments about information collection must be submitted to the Office of Management and Budget by May 4.

According to the notice, FDA is proposing to define the term "material change" to mean "a change in the organoleptic, nutritional, or functional properties of a food, caused by irradiation, that the consumer could not identify at the point of purchase in the absence of appropriate labeling." FDA is also proposing to permit substitution of the word "irradiated" with "pasteurized" "provided the food processor notifies the agency that the process used "meets the criteria specified for the use of the term 'pasteurized' in the Federal Food, Drug, and Cosmetic Act and the agency does not object to the notification." The rule would amend 21 CFR part 179.

Current labeling requirements for irradiated foods were adopted in 1986; thereafter, the Food and Drug Administration Modernization Act required FDA to seek public comment on whether changes should be made to the rule. The agency published an advanced notice of proposed rule-making in 1999 in response to the mandate, seeking public comment on the existing rule and suggestions for possible revisions. More than 5,500 comments were submitted, with the majority urging the agency to retain existing requirements. Some commenters apparently called for alternate wording, such as "cold pasteurization" or "electronic pasteurization." FDA next conducted focus group research across the country, and then the president signed into law the 2002 Farm Bill, which included provisions regarding use of the term "pasteurization" in irradiated food labeling and requiring FDA to seek public comment on changes to the food-labeling regulations.

To implement the 2002 law, FDA published guidance on a petition process to request approval for labeling foods treated by irradiation and noted that it was an interim process that would be used until final regulations were adopted. According to FDA, no petitions were submitted requesting the use of alternative labeling for irradiated foods. The proposal set forth in this FDA notice acknowledges that "irradiation has various effects on foods," although the agency indicates it is unaware of any nutritional changes in the foods it has approved for irradiation.

Discussing the types of changes that FDA considers material, the agency cites the examples of irradiated bananas and spices. According to FDA, because consumers expect bananas to ripen quickly and may want to use them at a very ripe stage for making banana bread, they may find irradiated bananas to be unsuitable for their planned uses, and thus, such products must be labeled. The agency distinguishes spices irradiated to control microbial growth, noting that they will likely also have their shelf life extended. "FDA tentatively believes that the extension in shelf life in this case does not have the potential to be detrimental to the consumer (e.g., to prevent the consumer's planned use of the food) because the irradiated spice can be used identically to an unirradiated spice." Thus, FDA suggests that the extension of a spice's shelf life is not material information the consumer needs to know. *See Federal Register*, April 4, 2007.

[2] Monsanto Seeks Warnings and New Guidance on Milk Ad Claims

Monsanto Corp. has **requested** that FDA and the Federal Trade Commission (FTC) take action against dairies that claim their milk comes from cows not treated with an artificial growth hormone. According to Monsanto, milk is milk whether or not the animals are treated with recombinant bovine somatotropin (rBST), which it manufactures, and the dairies are misleading consumers by saying anything to the contrary in their ads and charging more for their products.

Specifically, Monsanto is urging FDA to issue warnings to "those manufacturers and producers not making an effort to supply proper context or qualification to any claim with respect to the absence of milk from animals supplemented with rBST," reexamine its 1994 guidance with respect to "proper context," and "publish a clearer, stronger guidance addressing the types of labeling practices that currently dominate the marketplace." Monsanto is asking the FTC to conduct an investigation into "current advertising practices regarding milk and rBST."

Included in the company's submissions are numerous examples from processors such as Kleinpeter Dairy ("Many people believe that rBGH causes premature puberty in children."), Alta Dena ("No rBST in all of our products means better health and happier cows."), Berkeley Farms ("Not all milk is created equal. At Berkeley Farms, we make sure our milk is certified rBST hormone-free."), Borden ("Since 1857, Borden has taken a lot of pride in providing customers with premium, great tasting dairy products. That's why we work exclusively with farmers that supply 100% of our milk from cows that haven't been treated with artificial hormones."), and Stoneyfield Farm ("Concerns regarding the potential impacts of rBGH on cow health and the economic viability of the family farmer, as well as the clear customer preference that we not allow its use, lead us to stand firmly behind our policy not to buy milk from cows treated with the genetically engineered bovine growth hormone, rBGH.").

Also included among the company's submissions is a 2003 letter to the FDA pointing out that "Milk labels that make claims regarding BST, rBST or rBGH are often false or misleading to consumers." Officials from several of the dairies targeted by Monsanto reportedly agreed that the milk from rBST-treated cows is no different from any other milk, but they contend they provide rBST-free milk because their consumers ask for it. A Dean Foods spokesperson was quoted as saying, "This is a small niche product." Monsanto sued Oakhurst Dairy in

Maine in 2003 for its product labeling; the case settled when the dairy agreed to add a statement indicating that FDA had found no significant difference in milk from cows treated with the synthetic hormone. Additional details about that case appear in issues 39, 58 and 62 of this Report. *See The Boston Globe*, April 4, 2007.

[3] FDA Extends Comment Period for Cloning Risk Assessment Drafts

FDA has **extended** to May 3, 2007, its comment period for draft documents on the safety of cloned animals. The extra 30 days will ensure "adequate time," according to FDA, for the public to review the risk assessment, risk management plan and industry guidance issued in January 2007.

The revised deadline was instituted after FDA officials reportedly received a letter from several industry and consumer groups questioning its decision to approve cloning. One petitioner, the Center for Food Safety, recently published a report criticizing the agency assessment as flawed, although independent experts have apparently backed its scientific process. "To say the FDA didn't do its job or looked at only a handful of studies is negative hyperbole," Maureen Storey, Ph.D., director of the University of Maryland's Center for Food, Nutrition, and Agriculture Policy, was quoted as saying. *See Business Week.com* and *Food Navigator USA.com*, April 2, 2007; *Federal Register*, April 3, 2007.

[4] FDA Blocks Wheat Gluten Imports Implicated in Pet Food Recall

FDA has **blocked** wheat gluten imports from a Chinese company identified as the source of contamination in a recent pet food recall. FDA reportedly found melamine, a plasticizer also used in Asia as a fertilizer, in wheat gluten traced to Xuzhou Anying Biologic Technology Development Co., based in Wangdien, China. The gluten, which acts as a thickener in wet food and some diet-formula dry foods, has allegedly caused an undetermined number of animal deaths, although it remains unclear whether the ingredient has entered the human food supply. "To date, we have nothing that indicates it's gone into human food," said FDA's director of emergency operations. "We have a bit more investigation to do." *See Associated Press*, March 30 and April 2, 2007; *The Boston Globe*, April 3, 2007.

Canada-based Menu Foods last month recalled more than 60 million cans and pouches of "cuts and gravy" style food after receiving reports of kidney failure in cats and dogs that had ingested the products. Del Monte Foods Co., Hill's Pet Nutrition, Inc. and Nestlé Purina PetCare Co. also took several wet and dry products off the shelves. *See Associated Press*, March 30, 2007.

Department of Health and Human Services (HHS)

[5] NIEHS to Discuss Soy Estrogens in Formula and Infant Development

The National Institute of Environmental Health Sciences (NIEHS) has **announced** that senior investigator Walter Rogan will sponsor a meeting with experts in pediatric endocrinology, psychology, epidemiology, and nutrition to discuss soy estrogens and infant development. According to the notice, NIEHS has been studying the potential for estrogenic isoflavones in soy formula to "act as pharmacologic estrogens in infants by prolonging anatomical and biochemical markers in infants." The results are apparently becoming available, and

investigators are planning "what, if any, steps to take next." The public is invited to attend the meeting, and registration is required. *See Federal Register*, April 2, 2007.

[6] NTP Requests Public Comments on Nominations for Toxicology Studies

The National Toxicology Program (NTP) is **requesting** public comments that (i) address its recommendations regarding nine substances nominated for future study and (ii) provide information relevant to these nominations. As part of a formal review process, NTP routinely investigates substances "judged to have high concern as possible human health hazards," and those "for which toxicological data gaps exist." Substances about which NTP is currently soliciting comments include the artificial butter flavoring components, acetoin and diacetyl; and nanoscale materials, including nanoscale gold and silver. Comments should be submitted by May 10, 2007. *See Federal Register*, March 29, 2007.

U.S. Department of Agriculture (USDA)

[7] FSIS Announces Codex Alimentarius Commission Meeting on Food Labeling

USDA's Food Safety and Inspection Service (FSIS) has **announced** a public meeting on April 10, 2007, to discuss agenda items and draft U.S. positions for the April 30-May 4 meeting in Ottawa, Canada, of the Codex Committee on Food Labeling. Matters about which FSIS seeks comments include (i) a draft action plan for the implementation of a global strategy on diet, physical activity and health, (ii) labeling provisions in draft Codex standards, (iii) guidelines for labeling organically produced foods, (iv) labeling genetically engineered foods and food ingredients, (v) a proposed draft amendment to the general standard for labeling prepackaged foods with a quantitative declaration of ingredients, and (vi) a proposed draft definition of advertising related to nutrition and health claims. *See Federal Register*, April 3, 2007.

[8] FSIS Announces Ongoing Meetings About Risk-Based Inspection Program

On April 4, 2007, USDA's Food Safety and Inspection Service (FSIS) **announced** that it would hold hearings in April to consider various aspects of its risk-based inspection program for meat and poultry processing plants. According to FSIS, current practices, requiring inspections of every plant at least once every shift, could be improved by focusing on those facilities presenting the greatest risks. The first meeting, to address "the algorithm the Agency intends to use to compute risk-based inspection levels for processing establishments, took place on April 2. The second meeting, scheduled for April 5, will focus on "the issue of attributing illness to food." Thereafter, additional meetings will be held April 25 and 30 to consider "production volume" and "industry data," respectively. According to the notice, a fifth meeting will be held at a date to be announced to consider "the expert elicitation process." *See Federal Register*, April 2, 2007.

Litigation

[9] Kansas Beef Producer Wins Right to Test Cattle for BSE

A U.S. district court has determined that a Kansas meatpacker may test each of the approximately 300,000 head of cattle it slaughters annually to determine whether the animal was infected with bovine spongiform encephalopathy (BSE).

***Creekstone Farms Premium Beef, L.L.C. v. USDA*, No. 06-0544 (D.C. District Court, decided March 29, 2007)**. The court determined that USDA's denial of Creekstone's request to purchase BSE test kits was unlawful, but delayed the effective date of its ruling until June 1, 2007, to give the government time to determine whether it will appeal the decision. Before discussing the merits of the case, the court determined that the issues were not mooted when Japan lifted its ban on beef imports from the United States. The court further found that Creekstone had standing to bring the action because it had alleged that its revenues had dropped by 35 percent due to BSE-related concerns and that its customers are apparently prepared to buy more Creekstone beef at a higher price if it were tested for BSE.

The court disagreed with Creekstone as to whether the USDA could regulate the "use" of BSE test kits as "analogous products" under the Virus-Serum-Toxin Act. Nevertheless, finding that the agency's authority extends only to products that are (i) "intended for use in the treatment of domestic animals" and (ii) "worthless, contaminated, dangerous, or harmful," the court ruled that it could not regulate BSE test kits because they are not used for treatment. "There is no known treatment or cure for BSE, and BSE test kits are used only on animals that are dead," according to the court. The court appeared to agree with USDA that testing slaughter-age cattle is unlikely to identify BSE, even in infected cattle, but contended that the testing's purported lack of value would be a matter for the Federal Trade Commission or the Department of Commerce to address. Creekstone has already built a state-of-the-art laboratory to conduct the tests and is reportedly preparing its testing protocols. *See meatingplace.com*, April 3, 2007.

[10] U.S. Supreme Court Declines to Review Decision Ending Corporate Farming Ban

The U.S. Supreme Court has decided not to review a lower court decision that ended a constitutionally based ban on corporate farming in Nebraska. *Gale v. Jones*, No. 06-1045 (U.S., denying petition for writ of *certiorari*, Apr. 2, 2007). Further details about the Eighth Circuit court's opinion and ruling appear in issue 196 of this Report. Nebraska voters approved the ban in 1982; it prohibited corporations or syndicates from acquiring an interest in land used for farming or ranching. Organizations that support such bans are reportedly planning to seek provisions in the 2007 Farm Bill that would curtail corporate concentration in agricultural markets. *See The San Francisco Chronicle*, April 2, 2007.

[11] Sugar-Substitute Makers to Spar in Court

The company that manufactures artificial sweeteners such as Equal® and NutraSweet® will be trying false-advertising claims under the Lanham Act against the manufacturer of Splenda® in a federal district court in Pennsylvania beginning in April 2007. *Merisant Co. v. McNeil Nutritionals, L.L.C.*, No. 04-5504 (U.S. District Court, Eastern District of Pennsylvania). According to Merisant Co., claims that Splenda® is "made from sugar" and "tastes like sugar" are false and misleading, both literally and impliedly, and have caused actual consumer confusion and damage to Merisant in violation of Pennsylvania's common law of unfair competition. Merisant is seeking a ban on the use of such statements on Splenda® products, an order directing McNeil to institute a corrective advertising campaign, compensatory damages, treble and other available exemplary damages, costs, and attorney's fees. *See The Legal Intelligencer*, March 8, 2007.

U.S. District Court Judge Gene Pratter paved the way for trial with a recent **order** denying McNeil's motion for summary judgment. She found that genuine issues of material fact existed as to whether (i) Merisant waited too long after the launch of Splenda® to bring its legal challenge, (ii) Merisant's "implied falsity" claims cannot be proved because the advertising statement is literally true, and (iii) Merisant is not entitled to disgorgement of McNeil's profits.

The court also denied motions filed by both parties to exclude the other's expert-witness testimony and granted Merisant's motion for partial summary judgment which sought to preclude McNeil from presenting an affirmative "unclean hands" defense. McNeil had argued that Merisant also tried to present its products as "natural," and the court indicated that "the defense of 'unclean hands' is not a mere 'they did it too' defense, but instead serves as a shield against a plaintiff's claims when the plaintiff has engaged in 'egregious misconduct.' Thus, McNeil finds itself in the peculiar position of not wanting to argue that Merisant's past conduct is egregious, because that would seriously risk the implication that McNeil's own 'factually indistinguishable' conduct rises to the same level."

In a related development, Citizens for Health, an advocacy organization devoted to natural health choices, has launched a hotline for consumers who believe they are experiencing side effects from the use of Splenda®. The organization filed a petition in April 2006 with FDA, calling on the agency to revoke its approval of sucralose, the main ingredient in Splenda®. Further details about the petition appear in issue 165 of this Report. According to Citizens for Health, FDA has ignored its petition, so it has decided to document its concerns. Board Chair Jim Turner stated, "I encourage consumers to contact us if they have suffered any side effects from the use of the chlorinated artificial sweetener Splenda and to join us in demanding that FDA immediately conduct case studies on possible side effects from its use." *See Citizens for Health News Release*, March 21, 2007.

Meanwhile, a number of Internet blogs, including "**Sustainable is Good**," were reporting in March 2007 that the makers of Splenda® have bought hundreds of negative domain names to prevent anyone from establishing Web sites critical of the product. Among the domain names co-developer Johnson & Johnson now purportedly owns are "splendakills.net, .org, .biz, .info," "splendapoison.com, .net, .org, .biz, .info," "splendatoxicitycenter.com, .net, .org, .biz., .info," and "bittertruthaboutsplenda.com, .net, .org, .biz, .info." According to the blog, "The mere fact that a major corporation and maker of a product has bought and owns domain names with their product name and the words 'poison,' 'kills,' and 'sucks,' and 'victims' is amazing. Under what possible scenario does Johnson & Johnson envision that someone would create the website 'victimsofsplenda.com.'"

Other Developments

[12] RWJF Pledges $500 Million to Fight Childhood Obesity

The Robert Wood Johnson Foundation (RWJF) has pledged $500 million over five years to fight childhood obesity. Hoping to reverse the childhood "obesity epidemic" by 2015, the foundation aims to make healthy foods affordable and accessible, as well as provide for physical activity in schools and

communities. Its efforts will also target "at-risk" groups, which RWJF identifies as African-American, Latino, Native American, Asian-American, and Pacific Islander children. "The leadership statement this makes is tremendous," former U.S. Surgeon General David Satcher, M.D., reportedly said of the commitment. "With so many serious problems in health and health care, RWJF's investment highlights just how critical this problem has become and is a call to all the nation that past efforts have been too small, too slow and too fragmented." *See PR Newswire*, April 4, 2007.

[13] Watchdog Group Claims Malt-Liquor Beverage Aimed at Underage Drinkers

"This is a shameful ploy to market malt liquor to the Lunchables set," charged a Center for Science in the Public Interest spokesperson in a recent press release criticizing Spykes, a malt liquor beverage manufactured by Anheuser-Busch. The 2-ounce beverages, advertised on **www.spykeme.com**, come in mango, melon, lime, and chocolate flavors and contain caffeine, ginseng and guarana – "ingredients typically associated with energy drinks that are popular with young people," claims CPSI. The consumer watchdog is calling on state attorneys general to investigate Anheuser-Busch's marketing tactics, which allegedly include offers of "teen-friendly accessories like Instant Messaging icons and cell phone ringtones" on the Spykes Web site. *See MSNBC.com*, March 30, 2006; *CSPI Press Release* and *The Wall Street Journal*, April 4, 2007.

In a related development, health advocates in Scotland have requested that stores stop selling carbonated apple juice bottled to resemble champagne. "It's irresponsible to market and package juice for children as if it is alcohol, particularly by such a famous global brand as Disney," a representative of Alcohol Focus Scotland said about Disney PartyFizz, which campaigners have likened to "cigarette sweets." Celebratory children's drinks have reportedly gained popularity as parties and events become more lavish. "I don't share the view that it will encourage children to drink alcohol. These concerns are not well founded," a British Soft Drinks Association spokesperson was quoted as saying. "I am sure children are quite aware that they are drinking fizzy apple juice and not alcohol." *See The Scotsman*, March 25, 2007;

Media Coverage

[14] Andrew Martin, "Will Diners Still Swallow This?," Jane Brody, "You Are Also What You Drink"; *The New York Times*, March 25 and 27, 2007

"Customers have come to associate huge quantities of food with value, a proposition that makes reducing portions difficult," writes *Times* reporter Andrew Martin in an article about the "super-sized" dilemma facing restaurateurs and consumers alike. Martin explains that although some chains like T.G.I. Friday's now offer reduced servings at lower costs, the challenges go beyond simply promoting smaller or healthier meals. "They don't want to do it because it brings in less money. They have no incentive to do it," said Marion Nestle, Ph.D., who also noted that Wendy's eliminated its 32-ounce "Biggie" drink by making it a "medium." Restaurants that market smaller plates, however, apparently hope that the tactic will attract more patrons to offset the slimmer checks. "While the primary goal of smaller portions is to lure more customers," Martin concludes, "Friday's is also hoping that consumers who eat them will have room left for appetizers and desserts."

Jane Brody, writing for the *Times* "Personal Health" column, examines data suggesting that sweetened or oversized beverages contribute to weight gain. In her overview of "preferred drinks," Brody cites recommendations from the "Beverage Guidance System," which an expert panel developed after reviewing published reports on the health effects of various beverages. Supported by the Unilever Health Institute in the Netherlands, the experts claimed that fruit drinks and sodas account for "half the rise in caloric intake by Americans since the late 1970s," in addition to having "weak satiety properties." Some studies also attributed health benefits, such as protection against memory loss, to coffee and caffeine consumption, but warned against even moderate alcohol intake as potentially causing birth defects or breast cancer. Low-fat and skim milk, which ranked below coffee on the expert panel list, are also endorsed by Brody, who finds that the health benefits range from reduced coronary risk to increased bone density.

Scientific/Technical Items

[15] Researchers Find Placebo Effect in Relationship Between Exercise and Health

Harvard researchers have shown that physically active people who are told their activity constitutes exercise and satisfies the surgeon general's recommendations for an active lifestyle will decrease their weight, blood pressure, body fat, waist-to-hip ratio, and body mass index, without making any changes in diet or activity levels. Alia J. Crum and Ellen J. Langer, "Mind-Set Matters: Exercise and the Placebo Effect," *Psychological Science*, February 2007. They studied women who cleaned hotel rooms, telling some of them that what they did was actually exercise. After four weeks, the women who were given that information felt better about themselves, lost an average of two pounds, lowered their blood pressure by almost 10 percent, and were "significantly healthier as measured by body-fat percentage, BMI, and WHR." The authors conclude that such results "support the hypothesis that exercise affects health in part or in whole via the placebo effect" and "speak to the potentially powerful psychological control people have over their health."

[16] Sons of "High-Beef Consumers" More Likely to Have Low Sperm Count, Alleges Study

A University of Rochester Medical Center research team claims that mothers who consume more than seven beef meals per week might negatively affect their sons' fertility. S. H. Swan, et al., "Semen quality of fertile US males in relation to their mothers' beef consumption during pregnancy," *Human Reproduction*, March 28, 2007. Researchers, who analyzed sperm from 387 partners of pregnant women, concluded that "sperm concentration was inversely related to mothers' beef meals per week," with sons of high-beef consumers having a 24.3-percent-lower sperm concentration than average. "One way to determine if prenatal exposure to anabolic steroids is responsible for a change in sperm count would be to repeat this study in men born in Europe after 1988, when hormones were no longer permitted in beef sold or produced there," said lead researcher Shanna Swan, Ph.D., who also noted confounding factors such as pesticide exposure.

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Food & Beverage Litigation Update is distributed by
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