Food & Beverage

LITIGATION UPDATE

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Food & Beverage

LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Department of Agriculture (USDA)

[1] USDA to Revise Recordkeeping Regulations for Livestock Facilities

USDA's Animal and Plant Health Inspection Service has **proposed** amendments to "the regulations regarding the interstate movement of livestock" that would require livestock facilities and slaughtering and rendering establishments to retain certain records for five years. Livestock facilities are currently compelled to keep some records for two years, but slaughtering and rendering entities are not subject to similar record-retention provisions. The proposed rule would also oblige the operators of slaughter and processing plants to sign listing agreements to document their compliance with these regulations. "Requiring the retention of certain records for 5 years would allow us to trace the prior movements of diseased livestock further into the past than is currently possible, thus providing the opportunity to locate potentially infected or exposed livestock that might otherwise remain unidentified," stated the agency, which will accept comments on the proposed rule until September 5, 2008.

Food and Drug Administration (FDA)

[2] Agency Reverses Position, Says Products with HFCS May Be Labeled "Natural"

In a July 3, 2008, letter to the Corn Refiners Association, the FDA has indicated that products containing high-fructose corn syrup (HFCS) may be labeled "natural" if the synthetic fixing agent that is used in the HFCS production process does not come into contact with the high dextrose equivalent corn starch hydrolysate, which undergoes enzymatic reaction to produce HFCS. The fixing agent apparently holds the enzyme in place on a column and any unreacted agent is removed by washing before the starch hydrolysate is added. Thus, "we would not object to the use of the term 'natural' on a product containing the HFCS produced by the manufacturing process described" by a representative of the Archer Daniels Midland Co., who met with FDA at the request of the Corn Refiners Association in April 2008.

The agency added, "we would object to the use of the term 'natural' on a product containing HFCS that has a synthetic substance such as a synthetic fixing agent included in or added to it. We would also object to the use of the term 'natural' on a product containing HFCS if the acids used to obtain the starch hydrolysate do not fit within our policy on 'natural.'" In its letter, the FDA acknowledges that it previously took the position that the term

"natural" could not be used on a product containing HFCS, but changed its position when it learned that none of the fixing agent comes in contact with the main HFCS ingredient.

[3] FDA Bars Extralabel Use of Cephalosporin Drugs in Food-Producing Animals

FDA recently issued a **final rule** prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals. "We are issuing this order based on evidence that extralabel use on these drugs in food-producing animals will likely cause an adverse event in humans and, as such, presents a risk to the public health," FDA stated in a July 3, 2008, *Federal Register* notice.

The agency cited scientific evidence that cephalosporin extralabel use could comprise analogous human therapies by building bacterial resistance to this drug class. Cephalosporin drugs are among "the most widely used antimicrobial agents in human medicine," according to FDA, which noted their effectiveness in treating, among other serious conditions, *Staphylococcus aureus*, *Streptococcus pyogenes*, upper-respiratory tract infections, intra-abdominal infections, pelvic inflammatory disease, and diabetic food conditions. *See Meatingplace.com*, July 8, 2008.

Environmental Protection Agency (EPA)

[4] Agency Seeks Input on Children's Chemical Evaluation Program Modifications

EPA has **announced** that it will conduct a July 22, 2008, public meeting to allow comments on the modifications it intends to make to the Voluntary Children's Chemical Evaluation Program (VCCEP). Under this program's pilot, chemical companies and consortia agreed to sponsor testing and give EPA exposure and toxicity data on 23 chemicals posing a particular risk to children. The rate of review has apparently been sluggish, with critics noting, "in the six years of VCCEP's existence, only 12 chemicals have been peer-reviewed, and EPA has completed its review of only half of those 12." The modifications will establish due dates for assessment and make other changes to improve the program's performance. According EPA's notice, a particular focus of future VCCEP activity will be chemicals in indoor air, drinking water and food. *See Federal Register*, June 27, 2008; *Inside EPA*, July 6, 2008.

Codex Alimentarius Commission

[5] Various International Food Standards Adopted at 31st Codex Alimentarius Session

The Codex Alimentarius Commission reportedly adopted 35 international food standards at its 31st **session**, where member countries set benchmarks based on recommendations from the U.N. Food and Agriculture Organization and the World Health Organization. The dossiers approved by the commission included guidelines on food flavorings, gluten levels in gluten-free foods, product labeling, and mycotoxin contamination. In particular, Codex established definitions for natural and synthetic flavorings, advising their use in minimal levels to ensure safety. The commission also lowered the approved threshold for gluten in gluten-free products to 20 mg per kg (20 ppm) from 5g per kg (500ppm), the first changes to these rules since 1983.

The dossier on food labeling advocated "quantified" labeling for mixed, prepackaged foods if the

absence of ingredient percentages, by weight or volume, would mislead buyers. According to *Dairy Reporter.com*, the commission noted that when a product focuses on a certain ingredient through "words, pictures or graphics, or when the consumer would expect the ingredient to be present, the weight or volume of said ingredient must be included" or risk deceiving the consumer. Codex also tackled organic labeling guidelines, as well as those pertaining to nutrition and health claims.

The session further addressed foodborne mycotoxin contamination caused by potentially carcinogenic fungi. Codex found that mycotoxins in raw grains can reoccur in wheat flours, making it essential for bakeries to retain stability during processing. The EU legal limit for mycotoxins in finished products is 500 parts per billion (ppb), but studies have purportedly found commercial flour containing 750 ppb. In addition, Codex established best practices for preventing toxins in figs and adopted maximum levels for Ochratoxin A in raw wheat, barley and rye; aflatoxins in almonds, hazelnuts and pistachios; and 3-MCPD in liquid condiments containing acid-hydrolyzed vegetable proteins. *See Dairy Reporter.com*, July 7, 2008.

European Parliament

[6] EU Adopts Warning Labels for Six Artificial Food Colorings

The European Parliament this week adopted legislation requiring food and beverage manufacturers to label some artificially colored products with a health warning for children. MEPs reportedly endorsed the European Commission's Food Improvement Agents Package (FIAP), which includes four draft regulations governing food additives. Effective 18 months after official publication, FIAP applies to foods and beverages containing tartrazine (E102), quinoline yellow (E104), sunset yellow (E110), carmoisine (E122), ponceau (E124), and allura red (E129). These products must display warnings that their ingredients "may have an adverse effect on activity and attention in children," according to FIAP.

The legislation also compels all food additives, flavorings and enzymes on the market to undergo safety reassessments. This "common authorization procedure" will reportedly protect human health and consumer interests while centralizing approvals based on the scientific opinion of the European Food Safety Authority (EFSA). MEPs further agreed that approved additives must benefit consumers and serve a technological purpose; flavorings can earn the "natural" designation only if they are at least 95 percent natural in origin; and nanotechnology-enhanced products need separate limits. *See Food Product Daily.com*, July 9, 2008.

State/Local Governments

[7] California to Slaughter Thousands of Cows with Tuberculosis

Federal regulators have reportedly ordered the quarantine or slaughter of 16,000 cows in central California, where herds from three dairies tested positive for bovine tuberculosis (TB). One dairy has accepted a USDA buy-out to slaughter 4,800 cows at up to $3,000 per head, but the other two dairies may decide to weather long-term quarantines to preserve valuable genetic bloodlines.

State health officials have not named the implicated farms, but warned that 90 percent of infected cows do not show overt symptoms. The

California Department of Food and Agriculture (CDFA) has inspected approximately 150,000 cows since January, when a slaughterhouse first identified the disease during a routine inspection. This form of TB can spread to humans through the air or raw milk products, according to CDFA, which **noted** that the state's last documented bovine TB cases occurred in 2003. DNA tests have apparently linked two TB cases to a strain originating in Mexico, where the disease is more prevalent.

Meanwhile, trade organizations have registered concerns about the possible impact on California's $7.3 billion dairy industry. The outbreak has already affected interstate trade regulations governing the sale of cattle out of state, transportation for grazing in the dry season and livestock shows. USDA is currently drafting restrictions to require additional testing for California cows traveling across state lines. "One of the concerns is with trade agreements. Things like this can be used to renegotiate," a Western United Dairymen spokesperson was quoted as saying. *See The Associated Press*, July 9, 2008.

Litigation

[8] More Claims Against Applebee's for Understating Fat and Calories in Menu Items

A putative class action has been filed in a federal court in California, alleging that the company which owns the Applebee's Neighborhood Grill & Bar franchise has falsely advertised its Weight Watchers® menu items in violation of a number of state laws by understating their fat and calorie content. *Valiente v. DineEquity, Inc.*, No. 08-04241 (U.S. Dist. Ct., C.D. Cal., W. Div., filed June 26, 2008).

The named plaintiff seeks to certify a nationwide class of "[a]ll persons who ordered from and purchased a meal from the Weight Watchers® Menu at Applebee's between June 24, 2004, and June 26, 2008." He alleges violations of California's Business and Professions Code and Consumers Legal Remedies Act, as well as unjust enrichment, and requests an order enjoining defendant from engaging in conduct violating the law, restitution, attorney's fees, and costs.

In a related development, the restaurant industry, taking note of these types of class-action lawsuits, which have been filed in several jurisdictions, reports that operators are concerned about the trend among municipalities to mandate menu-board nutrition labeling, wondering if such mandates "will open the floodgates for similar litigation." According to a *Nation's Restaurant News* article, threats of such litigation "explain why the California Restaurant Association is supporting a menu-labeling bill that would offer some liability protections to operators in that state . . . by establishing that statutory compliance falls solely in the jurisdiction of local health officials and barring private citizens from taking any enforcement action." Information about nutrition label law initiatives and a related legal challenge appear elsewhere in this Update.

Without statutory protections, operators are cautioned to use disclaimers on their menus, noting possible variations in nutrition data depending on portion sizes, customization or other preparation factors. *See Nation's Restaurant News*, June 23, 2008.

[9] Organic and Dairy Associations Challenge Ohio's rBGH Rules in Court

The Organic Trade Association (OTA) and the International Dairy Foods Association (IDFA) have filed lawsuits in federal court seeking to bar Ohio's Director of Agriculture from enforcing new regulations that require certain information on product labels for dairy products that claim to be derived from cows not treated with synthetic recombinant bovine growth hormone (rBGH, also referred to as rBST). *OTA v. Boggs*, *IDFA v. Boggs*, Nos. n/a (U.S. Dist. Ct., S.D. Ohio, E. Div., filed June 30, 2008).

The regulations allow the statement "from cows not supplemented with artificial growth hormones" on product labels only if followed by the disclaimer "no significant difference has been shown between milk derived from rBST-supplemented and non-rBST supplemented cows." The rule also mandates type font, size, color, and location. While IDFA has no objection to use of the synthetic hormone, it claims that the state's rule is more restrictive than any other state's labeling requirements and even exceeds Food and Drug Administration requirements.

The OTA claims that the rule violates its members' First Amendment free speech rights, is preempted by federal law and funs afoul of the Commerce Clause by affecting interstate commerce. The IDFA raises similar claims and also contends that the rule violates its members' equal protection rights under the Fourteenth Amendment. IDFA filed a motion seeking to delay the rule's implementation pending the outcome of the litigation. According to an IDFA press release, Judge James Graham has already held a status conference, which IDFA's general counsel characterized as "very productive." *See OTA Press Release*, June 30, 2008; *IDFA Press Release*, July 7, 2008.

In a related development, a consumer advocacy organization, Institute for Responsible Technology, has announced that a documentary film challenging the safety of rBGH and discussing how it came to be approved, purportedly over scientific objection, is available online. "Your Milk on Drugs—Just Say No," can be accessed at www.ResponsibleTechnology.org.

[10] Sugar Substitute Maker Wins Preliminary Injunction in Trade Dress Suit

A federal court in Pennsylvania has issued an order preliminarily enjoining a company that makes private-label low-calorie sweeteners from manufacturing or distributing 100 and 200-count boxes of individual packets and bags of granular sucralose under the "Ahold" label. *McNeil Nutritionals, LLC v. Heartland Sweeteners LLC*, No. 06-5336 (U.S. Dist. Ct., E.D. Pa., decided June 26, 2008).

Private-label products are generally sold at lower prices than the national-brand product, in this case Splenda®. McNeil Nutritionals sued Heartland, which made the private-label product that mimicked the distinctive yellow packaging of Splenda®, in 2006 and sought a preliminary injunction requiring Heartland to recall its infringing packages. The trial court denied the motion, concluding that McNeil was unlikely to succeed on the merits of its claim because it "failed to demonstrate that the packaging of any of the products at issues was likely to cause consumer confusion." On appeal, the Third Circuit reversed, finding McNeil likely to succeed on the consumer confusion issue. The appeals court remanded the case for a consideration of the remaining trade dress infringement elements.

The trial court discussed the color-coding of

sugar substitute products, noting that Sweet'N Low® is sold in pink packets, Equal® is sold in blue packets, and Splenda® is packaged primarily in yellow. The court also discussed the particular features of Splenda® packaging, noting how similar the private-label boxes are, as well as the success McNeil has had since the product was introduced in 2001 and now represents 60 percent of the low-calorie sweetener market. Applying the legal standards under the Lanham Act, the court agreed with McNeil that "Heartland should be enjoined from continuing to manufacture and/or distribute products in the original Ahold packaging."

[11] Restaurant Association Challenges San Francisco Menu Law as Free Speech Restriction

The California Restaurant Association has reportedly sued San Francisco, challenging a law enacted in March 2008 that would require restaurant chains in the city to display calorie, carbohydrates, fat, and sodium information on menus along with a statement: "Recommended limits for a 2,000 calorie daily diet are 20 grams of saturated fat and 2,300 grams of sodium." Filed in federal court, the suit also includes a request for preliminary injunction to prevent the law from taking effect.

The trade organization alleges that the law constitutes compelled government-directed speech, which violates the First Amendment's free speech protections, and is preempted under the federal Nutritional Labeling and Education Act. The suit also contends that the law is "incomplete and misleading," lacks flexibility and will confuse customers. A regional vice president for McDonald's USA filed a declaration with the complaint, claiming that the requirement would "detract from our customer experience, create unnecessary barriers to service times and lead to customer and employee frustration."

San Francisco's city attorney responded in a statement, "it's outrageous that fat-peddling chain restaurants are asserting a First Amendment right to keep consumers uninformed about the nutritional contents of their menu items. The city's menu-labeling ordinance does not ban or restrict a single food item—it simply requires that consumers have better data to make informed choices." A similar challenge was filed against a New York City ordinance; the Second Circuit Court of Appeals ruled in April 2008 that the law could be enforced while the litigation is pending. *See San Francisco Chronicle* and *Product Liability Law 360*, July 8, 2008.

Meanwhile, a Santa Clara County Board of Supervisors member urged the public to support statewide legislation (S.B. 1420) that would require accessible nutrition information in fast-food restaurants. In a *Mercury News* article, board member Liz Kniss reported that Santa Clara County joined San Francisco in June 2008 by approving a menu-labeling ordinance. Thus, "[i]n Santa Clara County, consumers at fast-food restaurants will soon see the number of calories in a meal posted on the menu board, which will empower them to make healthier and more informed food choices." The article, which was co-authored by state Senator Alex Padilla (D-San Fernando Valley), cites a study recently published in the *American Journal of Public Health* finding that restaurant patrons with ready access to point-of-sale calorie information "ordered, on average, 52 fewer calories than those who did not see the information." *See Mercury News*, July 6, 2008.

In a related development, the final phase of New York City's *trans* fat ban reportedly took effect on

June 30. For the past year, restaurants were not allowed to use *trans* fats as spreads or frying oils. Now the ban extends to baked goods, frozen foods, cannoli, and doughnuts. The only restaurant food items exempt from the ban are those in the manufacturer's original sealed packages, such as candy and crackers. *See Newsday*, June 30, 2008.

[12] Court Orders USDA to Provide Notice and Comment on BSE Rule

A federal court in South Dakota has granted, in part, the motion for preliminary injunction filed by the Ranchers Cattlemen Action Legal Fund (R-CALF), which is seeking to stop the importation of live cattle over 30 months old from Canada. *R-CALF v. USDA*, No. 07-1023 (U.S. Dist. Ct., D. S.D., decided July 3, 2008). While the USDA rule allowing the importation will remain in effect, the agency must open this part of the rule ("over thirty months," or OTM, rule) to public comment and consider revising it if necessary.

According to the court, the agency failed to comply with the Administrative Procedure Act when it decided to allow such imports in November 2007 on the basis of comments it had received about the risk of bovine spongiform encephalopathy (BSE) from Canadian beef imports during notice-and-comment procedures that occurred in 2003 and 2004. Because the USDA delayed the implementation of the OTM rule when it implemented a rule allowing imports of Canadian cattle under 30 months of age in 2005, the court ruled that it could not rely on "an old record" to lift the delay on imports of OTM beef in 2007. Doing so, "[i]n light of the new cases of BSE in Canada and the dire consequences that would result from a BSE outbreak in the United States," said the court, "does not reflect reasoned decision-making."

[13] Lawsuits Begin in Nebraska Beef Recall

Several lawsuits have been filed in Ohio since Nebraska Beef Ltd. and The Kroger Co. recalled more than 5.3 million pounds of beef purportedly contaminated with *E. coli*. Food plaintiffs' lawyer William Marler announced that his firm was filing suit in state court on behalf of a woman who was allegedly hospitalized after eating beef patties she had purchased from Kroger in June 2008. According to Marler, the suit was filed June 30 in the Franklin County Court of Common Pleas. He reports that Kroger has recalled beef and beef products at least five times since 2001. On July 2, another law firm filed suit in an Ohio state court on behalf of Zachary Everhart who was allegedly infected with *E. coli* after eating meat purchased from Kroger. This suit apparently also names Nebraska Beef as the product supplier.

USDA's Food Safety and Inspection Service (FSIS) reportedly expanded the initial recall of 500,000 pounds because its investigation purportedly showed that Nebraska Beef's production practices "are insufficient to effectively control *E. coli*, O157:H7 in their beef products that are intended for grinding. The products subject to recall may have been produced under unsanitary conditions." FSIS also reportedly claimed that the meat processor "didn't take appropriate actions when positives were found."

A company spokesperson disagreed with the assessment, noting that, while it received FSIS notices on June 9 and 17 about positive test results, other companies also supplied product used in the ground beef at issue. The company claims that it followed appropriate protocol and did not know there was a potential for recall until June 29. *See Marler Blog*, June 29, 2008; *Product Liability*

Law 360, July 3, 2008; *Business Week*, July 7, 2008; and *Meatingplace.com*, July 7& 8, 2008.

Legal Literature

[14] Laura Fey & Harley Ratliff, "A Brave New World: The Dawn of Hyper-Complex Litigation," *Bloomberg Law Reports*, July 7, 2008

In this article, Shook, Hardy and Bacon lawyers **Laura Fey** and **Harley Ratliff** discuss the liability issues raised by the movement of products across national borders. They contend that "complex products litigation no longer begins and ends in local state and federal court. From the initial document collection to the ultimate resolution, the traditional model for defending these actions is becoming obsolete." Among the examples they highlight are food imports and recalls that have been "publicized extensively on plaintiffs' firm Web sites." The article discusses some of the concerns raised by litigation conducted in foreign jurisdictions and suggests that a coordinated approach "is critical to the successful and efficient resolution of every suit." The authors caution that positions taken in early, individual cases, "as well as the testimony given and discovery responses provided, can haunt the company in future cases." They recommend that corporate defendants "get the defense of these kinds of cases right the first time."

Other Developments

[15] A-B Agrees to Cease Manufacture and Sale of Alcoholic Energy Drinks

Anheuser-Busch Co. Inc. has entered an agreement with the attorneys general of 11 states to stop making and selling caffeinated alcohol beverages such as Bud Extra® and Tilt®. The states alleged that the company marketed these products in violation of consumer protection and trade practice statutes, failed to disclose to consumers what would happen if they drink these beverages and directed their product promotions to underage consumers. Illinois Attorney General Lisa Madigan, noting in a press release that the beverages are popular with young people "who often incorrectly believe that the caffeine in the drinks will counteract the effects of the alcohol," cited research showing more reckless behavior among college students who mix alcohol and energy drinks. She called on other companies to follow A-B's lead.

A-B agreed to settle the claims without making any admissions and, in fact, continues to allege that it obtained all necessary state and federal approvals for its products, marketed them in compliance with the law and directed its advertising to consumers ages 21 and older.

Under the settlement agreement, A-B will reformulate its products, discontinue promotions and related Web sites and "not produce any alcohol beverage that contains caffeine or other stimulants that are metabolized as caffeine, such as Guarana." The company also agreed to pay $200,000 to the attorneys general of Arizona, California, Connecticut, Idaho, Illinois, Iowa, Maine, Maryland, New Mexico, New York, and Ohio. The sum will be split among the states and used for attorney's fees and costs or for consumer education. The Center for Science in the Public Interest, which threatened to sue the company over the beverages, hailed the agreement, noting that it resulted from the "first alcohol-related initiative" of its litigation unit. *See CSPI* and *Ill. Atty. Gen'l Press Releases*, June 26, 2008.

[16] Meatpacking Plant Supervisors Arrested for Aiding Illegal Workers

Immigration and Customs Enforcement (ICE) agents reportedly arrested two supervisors from Agriprocessors Inc., charging them with helping illegal immigrants obtain fake identification documents to work at the kosher meatpacking plant and encouraging them to live in the United States.

Charged with aiding and abetting the use of fraudulent identification, Juan Carlos Guerrero-Espinoza and Martin De La Rose-Loera were taken into custody after a raid on the facility in May, when ICE agents arrested 389 workers, mostly undocumented immigrants from Latin America, at the Postville, Iowa, plant. According to a news source, the raid was the single-largest worksite operation by the Bush administration and revealed working conditions described as "medieval." The plant allegedly employed more than 900 people who were underpaid, physically abused, sexually harassed, and subject to extortion. An investigation is apparently ongoing. The raid has reportedly affected kosher meat supplies in markets and restaurants across the country. *See The Wall Street Journal*, July 5, 2008; *Meatingplace.com*, July 7, 2008.

[17] American Academy of Pediatrics Recommends Cholesterol Drugs for Youth

The American Academy of Pediatrics has recommended the use of statins, along with diet and exercise, for some children and adolescents whose "bad" cholesterol exceeds 190 milligrams per deciliter. The academy has called on doctors to begin cholesterol screening at age 2 in children with a family history of heart disease or unknown genetic risk factors and for all children by age 10.

The policy statement directs pediatricians to advise patients with very high LDL concentrations to increase physical activity and undergo nutritional counseling, but adds that health care providers should consider statins as an option for high-risk youth. The Food and Drug Administration has already approved one statin for children as young as 8, and scientific evidence reportedly backs the safety and efficacy of short-term statin use in this age group. The academy has also revised its position on dairy products, recommending reduced-fat milk and dairy products for children as young as age 1. *See American Academy of Pediatrics Press Release*, July 7, 2008.

The new guidelines have drawn significant media coverage for their stance on drug treatment. "Critics complain that there is no evidence that giving statins to children will prevent heart attacks later in life and that there is no data on the potential side effects of taking the drugs for decades," contends a July 10, 2008, editorial in *The New York Times*. "The ease of popping pills should not distract parents, health professionals or policy makers from the more arduous tasks of cutting back on junk foods, promoting healthy diets and putting physical education back into the schools." *See The Associated Press*, July 7, 2008.

Scientific and Technical Items

[18] Animal Study Links Poor Diet During Pregnancy to Health Damage in Offspring

A recent study has suggested that pregnant or lactating rats on diets high in fat, sugar and salt produced offspring prone to adiposity with increased blood levels of glucose, insulin, triglycerides and/or cholesterol.. S. A. Bayol, et al., "Offspring from mothers fed a 'junk food' diet in

pregnancy and lactation exhibit exacerbated adiposity that is more pronounced in females," *Journal of Physiology*, July 11, 2008. Researchers with the Royal Veterinary College and London's Wellcome Trust claimed that even rats weaned off their mothers' "junk food" diet retained the detrimental effects after adolescence despite switching to healthier foods. In particular, the offspring purportedly exhibited more fat around organs, a precondition for developing type II diabetes. The study authors further noted that female rats tended to become fatter than their male counterparts, which overall had higher levels of insulin and normal blood sugars. "Humans share a number of fundamental biological systems with rats, so there is good reason to assume the effects we see in rats may be repeated in humans," one researcher was quoted as saying. *See BBC News*, June 30, 2008.

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