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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

FDA Panel Rejects Food Dye Warning Labels

The Food and Drug Administration's (FDA's) Food Advisory Committee has reportedly rejected a proposal to require warning labels for artificial food dyes, thereby confirming its earlier position that "a causal relationship between exposure to color additives and hyperactivity in children in the general population has not been established."

The committee addressed the issue at a March 30-31, 2011, meeting, where it heard testimony from experts, consumers and advocacy groups like the Center for Science in the Public Interest (CSPI), which has long urged FDA to follow Europe's example in encouraging companies to switch to non-synthetic alternatives. "It is to the great shame of many U.S.-based food companies that they are marketing safer, naturally colored products in Europe but not the United States," opined CSPI Executive Director Michael Jacobson in a March 30, 2011, statement. *See The New York Times,* March 29, 2011; *NPR,* March 30, 2011.

In particular, the advisory panel considered a study commissioned by the U.K. Food Standards Agency that purportedly showed evidence of a link between some popular color additives and attention deficit hyperactivity disorder (ADHD) in children. Although the research bolstered the European Union's decision to require warning labels on certain foods, the FDA committee ultimately found that current data and clinical trials suggest that food coloring may aggravate ADHD in "susceptible children" but that the behavioral effects "appear to be due to a unique intolerance to these substances and not to any inherent neurotoxic properties." The panel concurred with a 1982 National Institutes of Health report concluding that "elimination diets should not be used universally to treat childhood hyperactivity," and recommended further studies "to address any questions that have been raised as to whether, and under what conditions, the continued use of these certified color additives is safe." *See Law360,* March 31, 2011; *UPI,* April 1, 2011.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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EPA Detects Trace Radiation in U.S. Milk

The U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) have issued a joint March 30, 2011, **statement** confirming traces of radiation in domestic cow's milk, which the agencies have been monitoring since an earthquake and tsunami in Japan compromised the Fukushima prefecture's nuclear power plant. A screening sample taken near Spokane, Washington, apparently contained 0.8 pCi/L of iodine-131, an amount "more than 5,000 times lower than the Derived Intervention Level set by FDA." Based "on very conservative assumptions," this level defines the threshold at which "protective measures would be recommended to ensure that no one receives a significant dose."

"Iodine-131 has a short half-life of approximately eight days," said the agencies. "These types of findings are to be expected in the coming days and are far below levels of public health concern, including for infants and children." *See FDA's Radiation Safety: New and Updated Information,* March 29, 2011.

U.S. Senate to Consider Food Safety Crime Bill

The Senate Judiciary Committee has sent to the Senate a food safety crime **bill** (S. 216). Designed to "strengthen criminal penalties for companies that knowingly violate food safety standards and place tainted food products on the market," the legislation would increase offenses from a misdemeanor to a felony, establish fines and give law enforcement the ability to seek prison sentences of up to 10 years. "The fines and recalls that usually result from criminal violations under current law fall short in protecting the public from harmful products," Leahy said in a statement. Details of the Food Safety Accountability Act, first proposed in summer 2010 by Senator Patrick Leahy (D-Vt.) and reintroduced in January, appear in **Issue 380** of this *Update. See Press Release of Senator Patrick Leahy,* March 31, 2011.

European Lawmakers Reach Impasse on Food from Cloned Animals

Representatives of the European Parliament and Council of the European Union (EU) have reportedly failed to reach an agreement on legislation that would have prohibited the sale of food produced from cloned animals. The impasse means the EU's 1997 law remains in effect; it requires government approval to sell milk and meat from cloned animals but does not ban cloning or importing food from cloned animals.

Lawmakers have been in agreement with EU consumers in wanting to ban cloned foods, but the recent clash centered over the labeling of food products from the descendents of cloned animals. Parliament proposed mandatory labeling of such products, but council members wanted labels on fresh beef only.

"We made a huge effort to compromise but we were not willing to betray consumers on their right to know whether food comes from animals bred using clones," Parliament members Gianni Pittella and Kartika Liotard said in a statement. "Since European public opinion is overwhelmingly against cloning for food, a commitment to label all food products from cloned offspring is a bare minimum. Measures regarding clone offspring are absolutely critical because clones are commercially viable only for breeding, not directly for food production. No farmer would spend £100,000 ($141,000) on a cloned bull, only to turn it into hamburgers."

Council members, however, expressed equal disdain with Parliament's demands. "The discussion failed because of European Parliament's inability to compromise on its request for mandatory labeling for food derived from offspring of cloned animals irrespective of the technical feasibility and the practical implications of such mandatory labeling," a council statement said. Hungary's minister of rural development was quoted as saying that Parliament's stance "in practice would have required drawing a family tree for each slice of cheese or salami." *See Press Releases for the European Parliament, Council of the European Union; Anchorage Daily News,* March 29, 2011.

LITIGATION

Eleventh Circuit Refuses to Recognize Nicaraguan Court Judgment for Banana Workers

The Eleventh Circuit Court of Appeals has affirmed a district court ruling finding that a $97 million judgment entered by a Nicaraguan court to compensate 150 Nicaraguan agricultural workers for injuries allegedly caused by workplace exposure to a pesticide is unenforceable under Florida law. *Osorio v. Dow Chem. Co.*, No. 10-11143 (11th Cir., decided March 25, 2011).

The appellate court agreed that (i) "the Nicaraguan court lacked subject matter jurisdiction and/or personal jurisdiction over the defendants"; (ii) "the foreign judgment could not be recognized in Florida because the judgment was 'rendered under a system which does not provide . . . procedures compatible with the requirements of due process of law'"; and (iii) "the Nicaraguan judgment could not be recognized under Florida law because doing so would be repugnant to Florida public policy."

The court declined to address whether Nicaragua "as a whole 'does not provide impartial tribunals'" and also noted that "nothing in the affirmed rulings is to play a collateral estoppel role in a subsequent court's litigation of the merits of the plaintiffs' personal injury claims." The defendants include the chemical company that supplied the pesticide and the company that used it on its banana plantations.

YoPlus Class Certification Ruling Remanded to District Court

Finding that the class definition approved by the district court was inconsistent with its analysis of the class certification requirements, the Eleventh Circuit Court of Appeals has returned litigation over the purportedly misleading digestive health claims for YoPlus yogurt to a district court in Florida. ***Fitzpatrick v. General Mills, Inc.*, No. 10-11064 (11th Cir., decided March 25, 2011)**. Additional information about the case appears in **Issue 296** of this *Update.*

When it decided to grant the plaintiffs' motion for class certification, the district court apparently defined the class as "all persons who purchased YoPlus in the State of Florida to obtain its claimed digestive health benefit." The defendant challenged this definition on the ground that it requires individualized fact-finding, and the court had specifically determined that common issues predominate over individualized issues.

According to the appellate court, the district court "conducted a detailed analysis of the requirements necessary for a class action," and its order was "a scholarly work reflecting careful attention to the requirements of Federal Rule of Civil Procedure 23, existing precedent and the factual background of this matter." Still, because the district court defined the class in such a way as to take "into account individual reliance on the digestive health claims," the Eleventh Circuit found it confusing and inconsistent with the district court's analysis, with which it agreed. The court vacated the class certification ruling and remanded the matter to the district court for further consideration.

DOJ Settles Antitrust Claims Against Dean Foods

The U.S. Department of Justice (DOJ) has reached a **settlement** with Dean Foods Co. over antitrust concerns about its acquisition of the Foremost Farms USA Coop.

Under the agreement, which will be published in the *Federal Register* for comment and must undergo court approval, Dean will "divest a significant milk processing plant in Waukesha, Wis., and related assets . . . including the Golden Guernsey brand name." The agreement also apparently requires Dean to "notify the department before it makes any future acquisition of milk processing plants for which the purchase price is more than $3 million." According to DOJ, the divestiture will "restore competition in the sale of milk to schools, grocery stores, convenience stores and other retailers in Illinois, Michigan and Wisconsin." *See Department of Justice Press Release*, March 29, 2011.

Court Pares Soup Labeling Claims Litigation

A federal court in New Jersey has granted in part the motion to dismiss filed by the Campbell Soup Co. in litigation alleging that consumers were misled by the company's lower-sodium labels, believing they were a healthier alternative to regular soups, which allegedly contain about the same levels of sodium as the more expensive low-sodium versions. *Smajlaj v. Campbell Soup Co.*, No. 10-1332 (U.S. Dist. Ct., D.N.J., decided March 23, 2011). The plaintiffs seek to represent a nationwide class of consumers, and named plaintiff Rosa Smajlaj has voluntarily dismissed her claims, so the suit will proceed with four other New Jersey residents as named plaintiffs.

The defendant sought to dismiss the claims under the plausibility pleading standard established in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and on the basis of federal preemption. The court determined that the claims of misleading labels were not preempted under federal law because they mirror federal requirements and thus would not impose inconsistent requirements on the defendant. Claims that the labels omitted information, however, were preempted according to the court, because the "Plaintiffs would have this Court impose a labeling requirement for the nutrient content of sodium that is inconsistent with the FDA's nutritional labeling regulations."

As to the claims raised under the state consumer fraud law, the court determined that the plaintiffs had alleged misleading representations with sufficient particularity to satisfy the Federal Rules of Civil Procedure. The court also found that the plaintiffs had adequately alleged their express warranty claims. Whether some of the class claimants had sufficiently alleged reliance on unspecified "marketing materials" and the company's Website claims about the product was a matter the court deferred to its ruling on a motion to certify the class. One plaintiff had sufficiently alleged such reliance.

Class Action Challenging "All Natural" Designation for Ice Cream Transferred

Relying on the first-to-file rule, a federal court in New Jersey has transferred a putative class action alleging false advertising for a Breyers ice cream product to a federal court in California that is considering similar litigation. *Catanese v. Unilever d/b/a/ Breyers*, No. 10-5755 (U.S. Dist. Ct., D.N.J., decided March 28, 2011). The plaintiffs in a number of cases have alleged that ice cream containing alkalized cocoa cannot be advertised as "all natural" because alkalized cocoa powder is chemically altered. The first such case was filed in a California federal court against Ben & Jerry's, a Unilever company, in September 2010. A nearly identical action involving Breyers products was also filed in a California federal court three days before the *Catanese* plaintiffs filed

their complaint. According to the court, "Conducting this class action in one forum will benefit both the public and private interests by avoiding duplicative litigation."

Information about a similar case filed in California in October 2010 appears in **Issue 370** of this *Update*. According to the district court that transferred the *Catanese* claims, the October 2010 lawsuit was voluntarily dismissed and refiled with a different plaintiff in a different California federal court shortly thereafter.

Companies Settle Dispute over Responsibility for 2008 *E. Coli*-Tainted Beef Recall

Nebraska Beef Ltd. has reportedly agreed to settle its lawsuit against Meyer Natural Foods LLC, and a federal court in Nebraska has apparently ordered the parties to file a motion to dismiss by April 25, 2011. Nebraska Beef recalled about 7 million pounds of beef in a 2008 *E. coli* outbreak linked to some 76 illnesses. According to a news source, some of the meat came from cattle that the defendant purchased and sent to Nebraska Beef's plant for processing. While the terms of the settlement have not been disclosed, Nebraska Beef, which contends the contamination did not originate at its facility, had been seeking a declaration that it was not required to indemnify Meyer for legal claims related to the recalled meat filed against Meyer. *See Fremont Tribune*, March 26, 2011.

Farmers and Seed Companies Want Monsanto GE Seed Patents Declared Invalid

A coalition of more than 50 trade organizations, seed businesses, farms, and farmers has filed a lawsuit in a federal court in New York, to stop Monsanto Co. from enforcing its genetically engineered (GE) seed patents against farmers whose fields become contaminated with the GE seeds. *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, No. 11-2163 (U.S. Dist. Ct., S.D.N.Y., filed March 29, 2011). Among other matters, the plaintiffs claim that the seed patents are invalid, because "only technology with a beneficial societal use may be patented," they violate "the prohibition against double patenting, each is anticipated or rendered obvious by prior art, and each fails to satisfy the requirements of written description, enablement and best mode."

The plaintiffs also allege that the patents are not infringed by farmers whose fields become contaminated with GE seeds, because the farmers do not intend to use them, "and Monsanto's patent rights in transgenic seed exhaust upon the authorized distribution by Monsanto to its customers." They further claim the company has "committed misuse," "is equitably stopped from enforcing" the patents and "commits trespass when its transgenic seed contaminates another."

At issue are some 23 patents, which, the plaintiffs contend, are "zealously" enforced by the company. According to the complaint, "Published reports and Monsanto's own statements suggest that roughly 500 farmers are investigated for patent infringement each year. Between 1997 and April 2010, Monsanto filed 144 lawsuits against farmers in at least 27 different states for alleged infringement of its transgenic seed patents and/or breach of its license to those patents." The plaintiffs also allege that "Monsanto has made accusations of patent infringement against those who never wished to possess its transgenic seed."

The complaint includes four claims for relief—declaratory judgments of patent invalidity, non-infringement, unenforceability and no entitlement to any remedy. The plaintiffs seek an injunction to stop the company "from taking any action to enforce any patent in suit" and an order for costs and attorney's fees.

Monsanto reportedly characterized the lawsuit as invalid and a "publicity stunt." According to the company, it has never sued farmers for the inadvertent presence of biotechnology traits in their fields. In a statement, the company said, "These efforts seek to reduce private and public investment in the development of new higher-yielding seed technologies. While we respect the views of organic farmers as it relates to the products they choose to grow, we don't believe that American agriculture faces an all-or-nothing approach."

The Public Patent Foundation, which filed the lawsuit on behalf of the coalition, disagreed that GE seed can coexist with organic seed. The foundation's executive director said, "[H]istory tells us that's not possible, and it's actually in Monsanto's financial interest to eliminate organic seed so that they can have a total monopoly over our food supply." *See Reuters* and *Public Patent Foundation Press Release*, March 29, 2011.

SPAM® Maker Sues Prem Maker for Trademark and Trade Dress Infringement

Hormel Foods, LLC has filed a complaint in a Minnesota federal court against a company that also makes a canned meat product, alleging that the company is infringing Hormel's SPAM® trademark, which consists of yellow lettering on a blue background. *Hormel Foods, LLC v. Zwanenberg Food Group (USA), Inc.*, No. n/a (U.S. Dist. Ct., D. Minn., filed March 30, 2011). The defendant allegedly began selling its product in October 2010 in a can with yellow labeling on a blue background. When Hormel sent a cease and desist letter, the company allegedly switched to a new design, white on a red background. Thereafter, the defendant resumed using the yellow on blue background label for products shipped to the Philippines and Japan.

According to the complaint, Hormel has produced 7 billion cans of SPAM® products, making the brand "a famous American icon. Its timelessness has earned it roles in films, a fan club and a highly coveted place in the Smithsonian. The SPAM® products even have a dedicated museum—the SPAM Museum—which opened in September 2001."

Hormel alleges federal common law trademark and trade dress infringement, trademark and trade dress dilution, unfair competition, violation of state deceptive trade practices law, and breach of contract. Apparently, the companies entered a contract in 2008 under which the defendant manufactured luncheon meat and chopped pork for Hormel Foods and agreed that it would not sell products with "labels or packaging that may, in Hormel Foods' reasonable judgment, be confusingly similar to the labels or packaging of any Products or any other products sold by Hormel Foods." Hormel seeks injunctive relief, an accounting, actual and treble damages, the destruction of all infringing materials, attorney's fees, and costs.

Brewer Challenges State Ban on Sale of Product with "Gonzo-Inspired Label"

Flying Dog Brewery has filed a lawsuit under the First Amendment, alleging that the Michigan Liquor Control Commission and its individual members violated its free speech rights by prohibiting the company from selling Raging Bitch Twentieth Anniversary Belgian-Style India Pale Ale. *Flying Dog Brewery, LLP v. Mich. Liquor Control Comm'n*, No. n/a (U.S. Dist. Ct., W.D. Mich., filed March 25, 2011). According to the complaint, a British artist, who once worked with journalist Hunter S. Thompson, designed Flying Dog's beer labels, including the one at issue. The defendants rejected Flying Dog's application for a license to sell the pale ale in the state, allegedly finding "that the proposed label which includes the brand name 'Raging Bitch' contains such language deemed detrimental to the health, safety, or welfare of the general public."

Claiming loss of sales and goodwill, the plaintiff alleges that its label constitutes expression protected by the First Amendment and seeks preliminary and permanent injunctive relief, an order mandating the issuance of a sales license to sell the pale ale, compensatory damages, attorney's fees, and costs. According to a company press release, the suit has the support of the Center for the Defense of Free Enterprise, which apparently "joined this important legal case because the issues raised have a profound impact on the right to freely engage in the marketplace." The company refers to its label as "gonzo-inspired," and describes it as depicting "a female dog drawn in the inimitable style for which [artist Ralph] Steadman has been internationally celebrated for half a century." *See Flying Dog Brewery Press Release,* March 28, 2011.

Seafood Spread Maker Sues Packer for Adding Egg to Product

A company that sells a variety of seafood spreads has sued one of its packers, which allegedly added undeclared eggs to the company's smoked salmon spread. *Sau-Sea Foods, Inc. v. Lukas Foods, Inc.*, No. 11-00104 (U.S. Dist. Ct., D. Me., filed March 23, 2011). The plaintiff apparently learned about the problem after the Food and Drug Administration (FDA) inspected the defendant's facility and discovered that eggs had been used in the spread, thus "posing a potential health hazard." A recall was immediately undertaken and widely reported in the media. Thereafter, FDA allegedly informed the plaintiff that its salmon spread "posed an acute, life-threatening hazard to health" and designated the recall as Class I.

Alleging breach of contract, breach of express and implied warranties, negligence, unjust enrichment, breach of implied contract, and negligent misrepresentation, Sau-Sea Foods seeks damages, interest, costs, and attorney's fees. While the company alleges damages exceeding the $75,000 jurisdictional minimum, it does not otherwise quantify its losses, which allegedly include "loss of revenues, loss of profits, injury to reputation, and loss of goodwill."

Century-Long Dispute Between Beer Makers Continues to Ferment in EU

Czech and U.S. brewers seeking to market their beers under the name "Bud," have apparently been at odds since the early 1900s. In the latest installment of the dispute, the Court of Justice of the European Communities has set aside a decision of the Court of First Instance which allowed the Czech brewer to oppose Anheuser-Busch's registration of "Bud" in Europe. *Anheuser-Busch Inc. v. Budějovický Budvar,* No. C-96-09 (E.C.J., decided March 29, 2011). While the Court of Justice upheld some of the lower court's rulings, it determined that the lower court erred (i) in the factors it relied on to decide if a "sign," or trademark, in opposition to a new registration was used in a sufficiently significant manner, and (ii) in holding that the use of the sign in opposition does not necessarily have to occur before the date of the application for new registration.

According to the Court of Justice, to prevent the registration of a new sign, "the sign in opposition must actually be used in a sufficiently significant manner in the course of trade and its geographic extent must not be merely local, which implies, where the territory in which the sign is protected may be regarded as other than local, that the sign must be used in a substantial part of that territory." In this regard, the court said that "account must be taken of the duration and intensity of the use of that sign as a distinctive element vis-à-vis its addressees, namely purchasers and consumers as well as suppliers and competitors," and that "the use made of the sign in advertising and commercial correspondence is of particular relevance."

The court also held, "as a general rule, where the sign concerned is used exclusively or to a large extent during the period between filing of the application for a Community trade mark and publication of the application [which was apparently the case here], that will not be sufficient to establish that the use of the sign in the course of trade has been such as to prove that the sign is of sufficient significance." The court remanded the case for further proceedings. According to a news source, the American brewer was allowed to sell Budweiser beer in North America over the past 100 years by agreement and tried to register the trademark in the European Union four times between 1996 and 2000. *See Courthouse News Service*, March 29, 2011.

SCIENTIFIC/TECHNICAL ITEMS

Food Packaging Pegged as Major Source of BPA Exposure

A recent **study** led by the Breast Cancer Fund and Silent Spring Institute reportedly concluded that both bisphenol A (BPA) and bis(2-ethylhexyl) phthalate (DEHP) exposures "were substantially reduced when participants' diets were restricted to food with limited packaging." Ruthann Rudel, et al., "Food Packaging and Bisphenol A and Bis(2-ethylhexyl) Phthalate Exposure: Findings from a Dietary Intervention," *Environmental Health Perspectives,* March 30, 2011. Researchers selected "20 participants in five families based on self-reported use of canned and packaged foods," and then directed these subjects to eat "their usual diet, followed by three days of 'fresh foods' not canned or packaged in plastic," before returning to their customary habits.

The results of urinary samples taken over the eight-day experiment reportedly demonstrated a significant decrease in BPA and DEHP metabolites during the fresh foods intervention. According to the Silent Spring Institute, these findings allegedly "show that food packaging is the major source of exposure to BPA and DEHP in children and adults, and a fresh food diet reduces levels of these chemicals by half, after just three days." *See Silent Spring Press Release,* March 30, 2011.

Research Alleges Link Between Meat Consumption, Cataracts

A recent study based on a 27,670 cohort enrolled in the European Prospective Investigation in Cancer and Nutrition has allegedly concluded that participants who limited their intake of meat and animal products reduced their risk for developing cataracts by as much as 40 percent. Paul Appleby, et al., "Diet, vegetarianism, and cataract risk," *American Journal of Clinical Nutrition,* published online March 23, 2011. Dividing subjects into groups ranging from those with the highest meat consumption to those who avoided meat and animal products altogether, researchers evidently found "a strong relation between cataract risk and diet group, with a progressive decrease in risk of

cataract in high meat eaters to low meat eaters, fish eaters (participants who ate fish but not meat), vegetarians, and vegans." The results reportedly indicated that, compared with those who ate the most meat, vegetarians reduced their cataract risk by 30 percent and vegans by 40 percent.

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FOOD & BEVERAGE LITIGATION UPDATE

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.