Food & Beverage

LITIGATION UPDATE

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Table of Contents

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LITIGATION UPDATE

Legislation, Regulations and Standards

U.S. Department of Health and Human Services (HSS)

[1] U.S. and Chinese Officials Issue Progress Report on Food Safety Initiatives

The United States and China have reportedly issued a joint progress **statement** on several food safety initiatives agreed to in December 2007. The report claims that the bilateral agreement has resulted in improved communication and helped coordinate regulatory systems by establishing designated points of contact, emergency contacts and notification thresholds for imports. The statement also outlines concrete steps taken to (i) implement an electronic certification system for Chinese exports; (ii) focus resources on inspections, supervision and laboratory testing standards; (iii) train Chinese officials on U.S. regulatory standards and requirements; and (iv) create a "cooperative mechanism" to notify both governments of significant public health risks. In addition, the Food and Drug Administration (FDA) has announced plans to open offices in Beijing, Shanghai and Guangzhou by the end of 2008. China this week granted diplomatic approval for the new outposts, which will assist local officials in inspection duties and increase the country's export capacity for safe foods, drugs and medical devices. "We are working very closely with the government to create a new strategy on the way we deal with imports," HHS Secretary Mike Leavitt said. "We see this office not just necessarily as an inspection group, it will be a capacity building group." *See Reuters* and *The Associated Press*, June 17, 2008; *HHS Press Release* and *The Wall Street Journal*, June 18, 2008; *Product Liability Law 360*, June 19, 2008.

Food and Drug Administration (FDA)

[2] Senior Staff Conclude Nanotechnology-Specific Regulation Not Needed

An FDA associate science commissioner has reportedly indicated that senior staffers "feel comfortable" regulating products incorporating nanoparticles within the agency's "present regulatory framework." While the FDA task force asked to consider agency readiness to deal with nano-engineered materials apparently recognized that biosafety issues could warrant a closer look, "for now, we just do not see the need for regulations written specifically for nano-engineered materials in the products FDA regulates." In 2004, the agency turned aside a petition seeking the labeling of products incorporating nanoparticles and materials and currently relies on manufacturers to tell the agency "if material in the product is in the nano range." A researcher with a consumer advocacy organization

referred to FDA's approach as a symptom of a "don't test, don't tell environment." *See CQ HealthBeat News*, June 17, 2008.

U.S. Department of Agriculture (USDA)

[3] FSIS to Review Food Defense Plans Adopted by Meat Processors

USDA has **announced** that its Food Safety and Inspection Service's (FSIS) Office of Food Defense and Emergency Response will conduct a survey on August 1, 2008, "to determine how many FSIS-regulated slaughter and processing plants have voluntarily adopted functional food defense plans." These plans strive to prevent intentional contamination of the U.S. food supply in an effort to cause death or widespread economic damage. FSIS has also published **guidance** recommending that these facilities take steps to (i) identify "vulnerable points at the establishment"; (ii) determine "what the risk factor is for each point"; (iii) develop "defense measure at each point that it has identified as high risk"; and (iv) "create a written plan to implement defense measures." FSIS has also noted that in addition to protecting consumer safety, such plans should "maintain a safe working environment for employees" and improve emergency response times. *See Meatingplace.com*, June 19, 2008.

European Commission (EC)

[4] EC to Promote Nanotechnology in Public Dialogue

The European Commission (EC) has reportedly announced plans to promote nanotechnology in an open dialogue aimed at assuaging consumer objections to the emerging industry. The project will involve additional nanotechnology research, as well as a consultation with member states, industry stakeholders and public advocacy groups to solicit feedback on potential regulatory action. The commission has estimated that the EU's future nanotechnology market will range from €750 billion to €2,500 billion by 2015 and create up to 10 million new jobs. "A reliable and stable regulatory framework is essential for enabling the EU's industry to fully exploit the advances of nanotechnologies. With the right structures in place they will boost innovation and contribute to growth, employment creation and competitiveness," EC Vice President Gunter Verheugen was quoted as saying. *See Food Navigator-Europe.com*, June 19, 2008.

Japan

[5] Japan Passes Law Restricting Waistlines to Curb Obesity

The Japanese government recently launched a public health campaign requiring companies and local governments to measure the waistlines of employees ages 40 to 74 during their annual checkups. The law, which reportedly applies to nearly 44 percent of the total population, requires men and women to trim their waistlines to 33.5 inches or 35.4 inches, respectively, in accordance with International Diabetes Federation guidelines. Those exceeding the limits and exhibiting signs of metabolic disease will receive nutrition counseling if they do not lose weight within three months and be recommended for diet "re-education" programs after six months. The Ministry of Health ultimately aims to cut nationwide health care costs by reducing the overweight population by 10 percent over the next four years and 25 percent over the next seven years.

Because companies and local governments face financial penalties for failing to achieve specific health milestones, several corporations have already adopted exercise and nutritional regimens to combat "metabo" – the Japanese euphemism for obesity – in their workforce. For example, the country's largest personal computer manufacturer has instituted waistline checks for all employees older than age 30 to avoid paying up to $19 million in potential fines.

Critics of the anti-obesity campaign, however, have accused the government of attempting to shift health care costs to the private sector by imposing overly strict guidelines, which will also encourage overmedication. A medical official at the Japan Society of Ningen Dock endorsed the effort but said the health ministry should also focus on anti-smoking messages despite the nation's powerful tobacco lobby. "Smoking is one of the causes of metabolic syndrome," Dr. Minoru Yamakado was quoted as saying. "So if you're worried about metabo, stopping people from smoking should be your top priority." *See The New York Times*, June 13, 2008.

State and Local Governments

[6] California Considers Legislation to Ban PFCs in Food Contact Substances

The California Assembly is considering a Senate bill (S.B. 1313) that would prohibit the manufacture, sale or distribution of any food contact substance, such as food packaging and non-stick cookware, containing perfluorinated compounds (PFCs) in concentrations exceeding 10 parts per billion. The ban, which would take effect January 1, 2010, would apply to PFC compounds PFOA (perfluorooctoanoic acid) and PFOS (perfluorooctane sulfonate) and their homologues. The Senate passed the bill by a vote of 22-15 in May 2008. According to the bill's author, Ellen Corbett (D – San Leandro), "Every consumer expects food packaging to be safe. But packaging with certain grease-proof coatings can contain perfluorinated chemicals (PFCs) that are not safe" because they have purportedly been shown to migrate into foods and have carcinogenic and developmental effects in lab animals. On June 18, the bill failed passage in an Assembly committee but reconsideration was granted.

[7] Oregon Lifts Restrictions on Home Deliveries of Wine and Beer

The Oregon Liquor Control Commission (OLCC) has unanimously approved legislation that permits grocers to make same-day deliveries of unlimited amounts of wine and beer to private homes. As of June 29, OLCC will allow grocery stores to distribute beer and wine to these residences before 9 p.m. if the customers placed their ordesr by 9 a.m. on the same day. The new rules, which do not apply to hard liquor sold in state-operated stores, replace temporary measures that limited the amount of alcohol per order. Although Oregon Partnership, a drug and alcohol awareness group, has contended that the changes will contribute to underage drinking, OLCC chair Phil Lang denied that the policy will have a negative impact on public safety. "The fact is, if there's a 21-year-old in the group, they can take their car or pickup to the store and buy an unlimited amount," Lang was quoted as saying. *See The Oregonian*, June 13, 2008; *The Progressive Grocer*, June 16, 2008.

Litigation

[8] Federal Court Defers to FDA in Dispute over Labeling HFCS Drink as "All Natural"

According to a news source, a federal court in New Jersey has dismissed claims that the manufacturer of a beverage containing high-fructose corn syrup (HFCS) deceived the public by promoting the product as "all natural." The court apparently based its ruling on federal preemption, leaving it to the Food and Drug Administration (FDA) to define the terms "natural" and "all natural." U.S. District Judge Mary Cooper reportedly stated, "This court will not determine that which the FDA, with all of its scientific expertise, has yet to determine, namely how the terms 'natural' and 'all natural' should be defined and whether either may be used on the label of a beverage containing HFCS. Instead, this court will allow the FDA, which has already set forth specific requirements for what must be included on beverage labels, to decide whether such a determination is necessary and warranted."

The ruling specifically applies to Snapple® drinks and, according to an attorney with the Center for Science in the Public Interest (CSPI), which has threatened similar litigation against Cadbury Schweppes and is backing such claims against Kraft, only those cases filed in New Jersey. CSPI's director of litigation reportedly claimed, "I doubt that other courts will follow [the N.J. case], because it is very much on the bleeding edge of preemption law, far ahead of what the [U.S.] Supreme Court has said." He was also quoted as saying, "we will keep suing companies outside New Jersey, so they should not take great comfort in having persuaded one judge."

Other legal commentators suggest that the decision simply maintains the status quo. While the FDA has not defined "natural," it does have a policy which provides that such products do not contain any artificial or synthetic substances of the type that would not normally be expected in food. An agency official reportedly responded to a specific request about HFCS by stating, "we would object to the use of the term 'natural' on a product containing HFCS." That said, the FDA has not formalized this approach through a rulemaking or published industry guidance. *See FoodUSAnavigator.com*, June 19, 2008.

[9] Chicken Producer Challenges USDA's Antibiotic Labeling Regulations

Tyson Foods, Inc. has filed a complaint against the U.S. Department of Agriculture (USDA), claiming that it violated administrative procedures when it changed its labeling policy for poultry products treated *in ovo* with antibiotics. *Tyson Foods, Inc. v. USDA*, No. 1:08-cv-01000 (U.S. Dist. Ct., D.C., filed June 11, 2008). Tyson, which stopped using antibiotics once its chickens are hatched, has, with USDA approval, been labeling and promoting its chicken products as raised without antibiotics since May 2007. Less than six months later, the USDA withdrew its approval but agreed to allow the company to use the antibiotic-free claim with qualifications rather than withdraw it altogether. Competitors challenged that action, which apparently led to the agency's decision in June 2008, withdrawing its approval of the qualified label. A lawsuit filed by Sanderson Farms, Inc. and Perdue Farms, seeking damages from Tyson is pending.

Tyson's complaint alleges that the USDA has ceased making a distinction between antibiotic prac-

tices applied while chickens are being "raised" and while the embryos are still in the shell (*in ovo*). The company argues that the agency "has failed to support properly its new regulatory approach" and acted "without following legally required procedures. . . . USDA instead acted precipitously, and on the basis of undisclosed *ex parte* submissions by a few of Tyson's competitors that neither Tyson nor other interested parties were able to review and comment upon." The complaint also alleges that the USDA "directed Tyson to change its labeling for more than 400 products by June 18th under its new regulatory standard" without imposing similar requirements on any other chicken producers. Alleging violations of the Administrative Procedure Act, Tyson seeks an order setting aside the agency's "new regulatory standard"; a declaration that the new standard is arbitrary, capricious and an abuse of discretion; an order barring the standard's enforcement and compelling the USDA "to follow the necessary procedures to issue a new rule on what practices may qualify for "Raised without antibiotics" labels"; and a prohibition on the enforcement of the USDA's June 18 deadline for the withdrawal of Tyson's qualified labels. *See The Wall Street Journal*, June 16, 2008.

In a related development, a plaintiffs' litigation firm in California is asking those "who purchased Tyson chicken advertised or labeled as raised without antibiotics, and would like to talk to us about our investigation," to contact the firm. Noting that Tyson's antibiotic-free advertising campaign has allowed the company to charge premium rates for its chicken and has been "a large-scale success," **Girard Gibbs LLP** appears to be poised to file consumer fraud litigation against the company.

[10] Meat Producer Settles *E. Coli* Death Claim for $13.5 Million

A meat producer that allegedly supplied a Sizzler franchise in Milwaukee with *E. coli*-contaminated product has reportedly settled claims filed by the family of a 3-year-old girl who died in 2000 after eating watermelon that had touched the tainted meat. DNA tests apparently confirmed that the strain responsible for the outbreak matched that of an unopened package of meat at the restaurant. A spokesperson for parent company Cargill Inc. was quoted as saying, "The death of Brianna Kriefall was truly a tragedy, and we feel deeply for how this has weighed on the family. We hope this settlement will help the family move forward and bring some sense of relief." Nearly 150 people who ate at two Milwaukee Sizzlers were apparently sickened during the outbreak, which caused the restaurants to close. Claims for $12 million in lost business will be tried in July 2008, said a news source. *See Product Liability 360* and *meatingplace.com*, June 16, 2008.

[11] Ohio Parents Seek Class Certification in Bisphenol A Lawsuit

Ohio parents, citing purported health risks from bisphenol A, have reportedly filed suit in federal court against the manufacturers of baby bottles and plastic cups containing the chemical. Seeking unspecified damages and class certification, the plaintiffs apparently allege that the companies knew about the risk but failed to disclose it and refer to scientific studies concluding that bisphenol A leaches from the bottles and cups into the liquids they contain. According to a press report, the plaintiffs filed their lawsuit a U.S. District Court in Columbus, Ohio, during the week of June 9, 2008. *See USA Today*, June 18, 2008.

[12] Second Circuit Refuses to Continue Stay of "No Fine" Order in Restaurant Menu Board Case

The Second Circuit Court of Appeals has refused the New York State Restaurant Association's request to extend the stay of a no-fine order entered after the association appealed a decision upholding New York City's regulation requiring chain restaurants to post calorie information on their menu boards. *N.Y. State Rest. Ass'n v. NYC Bd. of Health*, No. 08-1892 (2d Cir., motion denied June 16, 2008). Thus, while the court continues to consider the appeal, the city may begin imposing fines as early as July 18, 2008. The association contends that the law is preempted by federal regulations and violates restaurants' free speech rights. Further details about the case appear in issues 247, 257, 258, 259, and 263 of this Update. *See Product Liability Law 360*, June 19, 2008.

Legal Literature

[13] Tort Law Treatise Updated with Section on Strict Liability and Food Products

A section on strict liability as it applies to adulterated food has been added to *Modern Tort Law: Liability and Litigation*. Section 25.51 of volume 3 discusses how most courts apply the "consumer expectation" test rather than the "foreign-natural" test when considering whether a supplier of food can be held liable for injury caused by defective or contaminated food. The section also notes that "emotional distress damages may be recovered for defective food products," and indicates that circumstantial evidence "may be used to establish a prima facie defective food products claim in cases in which the specific harm-causing object or substance cannot be identified." According to the authors, "lay testimony coupled with a doctors [sic] diagnosis will be sufficient proof of causation."

Other Developments

[14] French Farmers Blame Vulture Attacks on EU Legislation

Farmers in the French Pyrenees have apparently blamed a recent spate of vulture attacks on a 2006 EU regulation requiring livestock owners to incinerate carcasses, thus depriving the scavengers of their usual diet: 150,000 tons of pig flesh. Although ornithologists have disputed the claims that vultures are preying on healthy animals, EU farmers reported 87 attacks in 2007, four times more than in previous years. In addition, several citizens have contended that the birds are crossing the mountains into France and as far as Belgium in search of adequate food supplies. "Vultures used to be our friends as they dealt with dead animals, but have now become predators. The state won't acknowledge this and is treating farmers as imbeciles," said Jean Lassalle, deputy of the Département of the Pyrénées-Atlantiques. *See The Telegraph*, June 16, 2008.

Scientific/Technical Items

[15] AMA Concludes High-Fructose Corn Syrup Unlikely to Pose Unique Health Risks

The American Medical Association (AMA) has reportedly concluded that high-fructose corn syrup (HFCS) "does not appear to contribute more to obesity than other caloric sweeteners." Presented at the AMA annual policy-making meeting in Chicago, the report stressed that further independent research is necessary to determine whether HFCS has long-term health risks not addressed by current

studies. "At this time there is insufficient evidence to restrict the use of high-fructose corn syrup or label products that contain it with a warning," stated AMA board member William Dolan. "We do recommend that consumers limit the amount of all added caloric sweeteners to no more than 32 grams of sugar daily based on a 2,000 calorie diet in accordance with the Dietary Guidelines for Americans." *See AMA Press Release*, June 17, 2008.

In a related development, the Grocery Manufacturers Association (GMA) has apparently released a science policy paper backing the safety of HFCS. The paper covers "significant peer-reviewed articles, regulatory considerations, food and beverage applications, and market insights," according to a June 16, 2008, article in *Food Navigator-USA.com*. GMA has asserted that "HFCS does not appear to contribute to overweight and obesity any differently than any other energy source," noting that the sweetener's composition is similar to sucrose (table sugar) and contains the same number of calories per gram. In addition, GMA pointed to the lower cost and processing benefits of HFCS, which better resists microbial growth and crystallization. "Consumers can rest assured that HFCS is just like any other caloric sweetener to be enjoyed in moderation in the context of a health-promoting lifestyle," said GMA Chief Science Officer Robert Brackett.

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