Food & Beverage

LITIGATION UPDATE

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Table of Contents

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GLOBAL PRODUCT LIABILITY LAW FIRM OF THE YEAR 2005|2006|2007 WHO'S WHO LEGAL

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LITIGATION UPDATE

Legislation, Regulations and Standards

110th Congress

[1] Dingell Floats Food-Safety Legislation; FDA Overhaul Contemplated

Representative John Dingell (D-Mich.), who chairs the House Committee on Energy and Commerce, has released draft **legislation** intended to improve the safety of imported foods and drugs. More specifically, the discussion draft would (i) give the Food and Drug Administration (FDA) new authority to issue mandatory recalls, (ii) require country-of-origin labeling, (iii) limit the number of ports through which food items could enter the country, (iv) prohibit the import of particular products until a foreign facility can prove that steps have been taken to remediate a reported problem, and (v) significantly increase civil monetary penalties for manufacturers or importers found to be in violation of the Federal Food, Drug, and Cosmetic Act. Among other provisions, the proposal would also impose a user fee for safety inspections of food and drug import shipments and prevent the Secretary of Health and Human Services from closing or consolidating any of the current FDA field laboratories without congressional approval.

The proposal's final section would require meat, poultry products and seafood containing carbon monoxide to be labeled with a safety notice stating, "Carbon monoxide has been used to preserve the color of this product. Do not rely on color or the 'use or freeze by' date alone to judge the freshness or safety of the product. Discard any product with an unpleasant odor, slime, or a bulging package." Dingell's "dear colleague" letter cites reports of melamine in pet food and antibiotic-tainted seafood as the impetus for the legislation. "Twice the amount of food is imported into our country as compared to ten years ago. Yet, the Food and Drug Administration examines less than one percent of these imports," he writes. According to a news source, while consumer groups have called for a number of the safety provisions in the proposal, concerns have already been expressed about the user fees. A Food and Water Watch lobbyist was quoted as saying that user fees, which give the appearance that industry is paying FDA salaries, "could lead to conflicts for an inspector." *See Congressional Journal's CongressDailyPM*, August 6, 2007.

Department of Health and Human Services (HHS)

[2] Independent Panel Reviews Bisphenol A's Potential Health Risks

An independent panel convened by the Center for the Evaluation of Risks to Human Reproduction (CERHR) of the National Toxicology Program (NTP) this week met to review data on bisphenol A's (BPA's) potential effects on human development and

reproduction. The meeting addressed a **draft expert panel report on BPA**, a chemical widely used in the production of polycarbonate plastic that may mimic the natural female hormone estradiol. Scientists considered evidence that exposure to BPA may result in birth defects, developmental problems, cancer, diabetes, obesity, and attention deficit disorder. On a scale ranging from "negligible concern " to "serious concern," the panel expressed "some concern" that fetuses, infants and children exposed to BPA may suffer from neural and behavioral effects. The panel also found "minimal concern" that (i) *in utero* exposure to BPA may affect the prostate; (ii) i*n utero* exposure to BPA causes accelerations in puberty; and (iii) exposure to BPA accelerates puberty in infants and children. In addition, the panel concluded there was "negligible concern" that BPA causes birth defects and malformations, and "negligible concern" for adverse reproductive effects in the general adult population exposed to BPA.

"The panel's finding means that we cannot dismiss the fact that exposure to this substance may be causing effects on reproductive health," CERHR Director Michael Shelby was quoted as saying. The panel also recommended further research to resolve any uncertainties, or raise or lower its levels of concern. The final expert panel report will be available in print and on the CERHR Web site in fall 2007, when CERHR will solicit public comments on the findings. Meanwhile, a group of 38 scientists, including colleagues at the National Institute of Environmental Health Sciences, have issued a consensus statement expressing concern about the use of BPA in food and beverage containers. *See NIEHS News Advisory*, July 31, 2007; *FoodProductionDaily-Europe.com*, August 1, 2007; *NBC News*, August 6, 2007; *NTP/CERHR Draft Meeting Summary*, August 6-8, 2007; and *Forbes.com*, August 8, 2007.

In related developments, Duke University Medical Center researchers have claimed that "neonatal exposure to [BPA] . . . is associated with higher body weight, increased breast and prostate cancer, and altered reproductive function." Dana C. Dolinoy, et al., "Maternal nutrient supplementation counteracts bisphenol A-induced DNA hypomethylation in early development," *Proceedings of the National Academy of Sciences*, August 2007. The study used agouti mice, which are usually slender and brown, to test the effects of BPA on mothers and offspring. The mother mice receiving BPA were more likely to give birth to yellow-coated offspring, an agouti variety more prone to obesity, cancer and diabetes. "The fact that the mice fed BPA had a yellow coat and likely would grow to be obese as adults demonstrates that this single substance had a system-wide effect," one researcher said. In addition, the study concluded that "maternal dietary supplementation, with either methyl donors like folic acid or the phytoestrogen genistein, negated" the effects of BPA. *See The Telegraph*, July 31, 2007.

[3] NTP Issues Background Documents for the Fungicide Captafol

The National Toxicology Program (NTP) has **announced** the availability of a draft background document for the fungicide captafol as part of its process for determining whether the substance should be listed as carcinogen in the *12th Report on Carcinogens* (RoC). The RoC expert panel will peer review the document during an October 15-16, 2007, meeting; the deadline for public comment is October 3. Those wishing to pre-register for the

meeting and provide oral comments must do so by October 10. NTP describes captafol as "a broad-spectrum fungicide that was widely used in the United States prior to the mid 1980s on fruits, vegetables, and other plants, as well as on timber products." The Environmental Protection Agency banned its use on all products except onions, potatoes and tomatoes, and, while many other countries have also banned it, the fungicide is still apparently used in Mexico. "The Food and Drug Administration continues to monitor for captafol residues in domestic and imported food. The potential exists for workers producing captafol and for agricultural workers because of past production and use of millions of pounds of captafol." *See Federal Register*, July 31, 2007.

European Union (EU)

[4] Foot-and-Mouth Disease Discovered in British Livestock

The EU this week banned all imports of British meat, livestock and dairy products after three farms in Guildford, Surrey, tested positive for foot-and-mouth disease. After culling more than 120 animals involved in the outbreak, British officials have reportedly confirmed that the disease strain resembles the virus isolated in a 1967 foot-and-mouth epidemic and now used in diagnostic laboratories and vaccine production. Their investigation has focused on a shared laboratory complex in nearby Pirbright, Surrey, where government and private researchers were allegedly using an identical strain to develop vaccines. Although both the government-funded lab and the private company have denied a security breach, officials have speculated that employees may have inadvertently transmitted the virus on their clothing or vehicles. The link to the laboratories was a "promising lead," according to Environmental Secretary Hilary Benn, "but we don't know for sure and therefore it is very, very important that people continue to be vigilant."

In 2001, Britain suffered a foot-and-mouth disease outbreak that resulted in the slaughter of 6 million animals and cost the country's agriculture and tourism industry an estimated $17 billion. EU representatives will continue to hear testimony from veterinary experts on whether to reopen its borders to some British livestock raised far from the outbreak's epicenter. Meanwhile, the British government has not ruled out deliberate sabotage. "The virus is tough but it is not quite superhuman," said Tony Wilsmore, the director of the Veterinary Epidemiology and Economics Research Unit at the University of Reading. "The risk of taking it out of the lab is small, and the risk of spreading it to an animal is also small. For both to happen you are multiplying two probabilities that are less than one, and when you do that, you get a lot less. If you multiply 0.1 by 0.1, you get 0.01. If you've got somebody who wants to spread it, that's a different story." *See Yahoo! News* and *Reuters*, August 6, 2007; *Sky News* and *The New York Times*, August 7, 2007; and *The London Times*, August 8, 2007.

Australia

[5] Australian Officials Discover Illegal Antibiotics in Asian Seafood

The Australian Quarantine and Inspection Service (AQIS) has reportedly discovered that one-third of sampled prawns, fish, crabs, and eels imported from Asian countries contained illegal antibiotics such as sulfonamides, tetracyclines, penicillin, fluoroquinolones, and quinolone. The seafood,

which came from China, Indonesia, Thailand, and Vietnam, tested in the range of parts per billion for the banned drugs, although inspectors did not identify any pesticide residue. While Australian law permits the use of antibiotics in fish farming, the resultant product must be antibiotic-free before going on the market. "[T]he worry about this is wherever you use antibiotics – and what this means is antibiotics were used in the production of those fish or those prawns – that means superbugs can develop, and can [remain] on the animal and come across to people and cause problems," an Australian public health advocate told the press. The government, which has reportedly known about the tests for three months, is now considering a hold on all Asian seafood similar to the detainment order in place in the United States. *See Australian Broadcasting Corporation Online*, August 3, 2007.

Litigation

[6] Deceptive Marketing Claims Filed Against Omega-3 Egg Producer

Washington state residents have filed a putative class action against a Washington state egg producer in federal court, alleging that it made deceptive advertising claims about eggs fortified with omega-3 fatty acids and failed to disclose material facts about such eggs in their marketing, advertising, labeling, and promotion. *Schneider v. Wilcox Farms, Inc.*, No. 2:07-cv-01160 (U.S. District Court, Western District, Washington, filed July 26, 2007). Plaintiffs are seeking to recover economic, statutory and punitive damages on behalf of a nationwide class and contend that some two dozen questions of law and fact are common to all class members. They allege unlawful, unfair, deceptive, and improper business practices; breach of warranties; breach of contract; conversion; and unjust enrichment.

According to the complaint, "Wilcox Defendants take advantage of consumers' limited knowledge of the difference between, and even the existence of, the different types of omega-3 fatty acids by grouping them together and disclosing them as a combined total, thereby artificially inflating the perceived amount of beneficial omega-3 fatty acids, and thus the perceived cardiovascular benefits associated with Omega-3 Eggs." In essence, the plaintiffs claim that consumers pay a premium price for Omega-3 Eggs, believing that omega-3 fatty acids provide cardiovascular benefits. Because all omega-3 fatty acids do not provide such benefits and because defendant's Omega-3 Eggs allegedly contain a type of omega-3 fatty acid without proven cardiovascular benefits, plaintiffs contend that defendants are improperly marketing their product as "The Healthy Way to Go." Plaintiffs further claim that defendants' eggs are advertised as containing less saturated fat than regular eggs, "thereby misleading consumers to believe that Omega-3 Eggs have significantly less saturated fat than regular eggs. In reality, however, Omega-3 Eggs contain less than .5 fewer grams of saturated fat than regular eggs."

[7] MDL Panel Consolidates Peanut Butter and Pet Food Lawsuits

The Judicial Panel on Multidistrict Litigation (MDL Panel) has consolidated 20 actions against ConAgra Foods, Inc. for damages allegedly incurred as a result of a *Salmonella* outbreak linked to its peanut butter. ***In re ConAgra Peanut Butter Prods. Liab. Litig.*, No. 1845 (J.P.M.L., consolidation and transfer ordered July 17, 2007)**. These cases, filed in federal district courts across the nation, as well as

34 potentially related actions pending in other federal districts, will be consolidated for pretrial proceedings in the Northern District of Georgia. The MDL Panel determined that relevant documents and witnesses were likely to be found in this district because "the manufacturing plant where the contamination occurred and the governmental agency that investigated the contamination are located there."

The MDL Panel also consolidated 13 cases filed against Menu Foods, Inc. for damages allegedly caused by pet-food products tainted by melamine from the imported wheat gluten used in the products. ***In re Pet Food Prods. Liab. Litig.*, No. 1850 (J.P.M.L., consolidation and transfer ordered June 19, 2007)**. Pretrial proceedings in these and 97 potential "tag-along actions" will be conducted in the District of New Jersey. According to the MDL Panel's order, "Pretrial proceedings are advancing well there and about one-third of all pending actions are already in this district."

In a related development, ConAgra is reportedly poised to reopen the manufacturing facility where the *Salmonella* contamination allegedly originated. Closed since February 14, 2007, the plant has apparently undergone $15 million in renovations, including roof repairs, new equipment and new processes to more effectively segregate raw materials from the finished product. *See FoodUSAnavigator.com*, August 9, 2007.

[8] Beverage Makers Settle Benzene Class Actions

Two months after a federal district court denied a motion to dismiss filed by soft drink makers sued for selling beverages with ingredients that tend to form benzene when exposed to light and heat, the cases reportedly settled. *Gonzalez v. PepsiCo, Inc.*, No. 06-2163 (U.S. District Court, Kansas, settled July 12, 2007). Further details about the court's denial appear in issue 217 of this Update. The beverage companies have apparently reformulated or agreed to reformulate their products to eliminate the possibility of benzene production, and they are making a product replacement program available. PepsiCo has also agreed to post a notice on its Web site stating, "Although the FDA and other food safety authorities have reiterated that there is no known health risk to consumers from the benzene levels found in soft drinks, in September 2006, Pespico reformulated its Diet Pepsi Wild Cherry product to minimize the formulation of benzene in that product." A news source has indicated that PepsiCo has also agreed to pay a confidential settlement amount to the class-action representatives and attorney's fees and expenses. *See LexisNexis Mealey's Litigation Report, Food Liability*, August 2007.

Other Developments

[9] CSPI Tests Allegedly Reveal Excessive *Trans* Fat in Fast-Food Fries

The Center for Science in the Public Interest (CSPI) has alleged that french fries served at Wendy's and Burger King outlets in New York City still exceed the maximum 2 grams of *trans* fat per day recommended by the American Heart Association. CSPI, which tested large orders of fries from five different McDonald's, Burger King and Wendy's restaurants, found that Wendy's fries contained 3.7 grams of *trans* fat per serving and Burger King's fries contained 3.3 grams of *trans* fat per serving. By comparison, McDonald's fries reportedly contained only 0.2 grams of *trans* fat per serving. "The new lab results don't necessarily mean that Burger King and Wendy's are violating

New York City's new requirement," a CSPI press release stated, referring to the city's ban on using *trans* fat in cooking and frying oils. The consumer group instead suggested that the chains' suppliers are pre-cooking the fries in partially hydrogenated oils prior to shipping. "If these chains want to claim they are switching to *trans*-fat-free frying oil, they need to switch it at the supplier as well as the restaurant. Burger King and Wendy's are really deceiving consumers with the public statements they've made about *trans* fat, which don't tell the whole story," opined a CSPI spokesperson. *See CSPI Press Release*, August 2, 2007; *FoodNavigator-USA.com*, August 3, 2007.

[10] Kroger Supermarkets to Switch to Milk from Hormone-Free Cows

The Kroger Co. recently announced that its stores will begin phasing out milk made from hormone-enhanced cows, replacing it with milk certified free of synthetic hormones. The grocery store chain, which operates 2,458 supermarkets in 31 states, said that the switch was "based on informed opinion and demonstrated consumer preferences: Kroger is being responsive to customers' needs." The decision has reportedly affected Monsanto Co.'s marketing of Posilac®, its brand-name version of recombinant bovine somatotropin (rBST), and prompted the company to further scale back production as additional retailers, including Starbucks Coffee Co., increasingly request hormone-free milk. While consumer groups such as The Center for Food Safety have applauded these campaigns, a Monsanto spokesperson has argued that, "With higher milk prices these days, it's disappointing that [Posilac] production technology – which can add efficiency at the farm gate and have a direct impact on consumer costs – is being denied." *See Associated Press*, August 5, 2007.

Scientific/Technical Items

[11] Study Alleges That Children Prefer Branded Foods to Identical, Unbranded Products

A Stanford University School of Medicine study has claimed that children younger than age 8 prefer branded foods to identical products in unmarked packaging. Thomas N. Robinson, et al., "Effects of Fast Food Branding on Young Children's Taste Preferences," *Archives of Pediatrics & Adolescent Medicine*, August 2007. Researchers surveyed 63 preschool-aged children, who were asked to indicate whether the food in McDonald's packaging tasted the same or better than identical foods in plain wrappers. Approximately 77 percent of the children reportedly preferred the McDonald's-labeled-french fries, while only 13 percent favored the unmarked version. "Kids don't ask for food from McDonald's, they actually believe that the chicken nugget they think is from McDonald's tastes better than an identical, unbranded nugget," one researcher was quoted as saying. In addition, the researchers concluded that "these findings are consistent with recommendations to regulate marketing to young children and also suggest that branding may be a useful strategy for improving young children's eating behaviors." *See Associated Press*, August 6, 2007; *FoodNavigator-USA.com*, August 7, 2007.

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