

Food & Beverage

LITIGATION UPDATE

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Table of Contents

Legislation, Regulations and Standards

- [1] Lawmakers Step into Bisphenol A Controversy1
- [2] Federal Agencies Announce Meeting to Discuss Foodborne Illness
Outbreak Strategies1
- [3] FDA Publishes Final Rule on Claims Linking Soluble Fiber to
Reduced Heart Disease2
- [4] FDA Withdraws Guidance for Testing Yellow Corn for StarLink® Residues2
- [5] Petition Seeks Regulation of Nano-silver as Pesticide2

Litigation

- [6] New Bisphenol A Lawsuit Filed in Missouri Against Makers of Baby Products ...3
- [7] Consumer Class Action Filed Against Tyson for “Raised Without
Antibiotics” Ads4
- [8] Appeals Court Panel Lifts Stay on NYC Menu Posting Rules5

Other Developments

- [9] Industrial Farm Animal Production Commission Releases Final Report5
- [10] TFAH Questions Safety of U.S. Food Supply6
- [11] Rising Food Prices and Commodity Shortages Spur Demands for Change6

Scientific/Technical Items

- [12] Study Finds Diet Choices Affect Environmental Impact More Than Food Miles ...7
- [13] Report Links Obesity to Foods Readily Available in Local Communities7

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LITIGATION UPDATE

Legislation, Regulations and Standards 110th Congress

[1] **Lawmakers Step into Bisphenol A Controversy**

Representative John Dingell (D-Mich.), who chairs the House Committee on Energy and Commerce, has requested that the acting chair of the Consumer Product Safety Commission respond to several questions about the bisphenol A in children's or other consumer products. The April 28, 2008, [letter](#) to Nancy Nord is co-signed by Representative Bobby Rush (D-Ill.) who chairs the Subcommittee on Commerce, Trade, and Consumer Protection.

Citing the draft report of the National Toxicology Program, which expressed "some concern" for adverse effects of exposure on fetuses, infants and young children, Dingell asks whether the commission has (i) "conducted any investigation or studies to determine if BPA [bisphenol A] is present in children's or other consumer products within its jurisdiction"; (ii) "determined whether BPA in those products qualifies as a 'hazardous substance'"; and (iii) taken any other action "to protect the public from, or to inform them about, exposure to BPA."

In a related development, Senator Charles Schumer (D-NY) has introduced a bill (S. 2928) that

would apparently ban bisphenol A in children's products. While the text was not available when we prepared this Update, the legislation, introduced April 29, 2008, has six co-sponsors and was referred to the Committee on Commerce, Science, and Transportation.

U.S. Department of Agriculture (USDA)

[2] **Federal Agencies Announce Meeting to Discuss Foodborne Illness Outbreak Strategies**

USDA's Food Safety and Inspection Service (FSIS), the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), and the Centers for Disease Control and Prevention (CDC) have [announced](#) a May 15, 2008, public meeting to discuss "improved information sharing and coordination during multi-jurisdictional foodborne outbreak investigations." The agencies are specifically seeking feedback pertaining to (i) "Stakeholders' perspectives on both successes and challenges to effective collaboration during multi-jurisdictional outbreaks" and (ii) "Ongoing projects and initiatives to improve foodborne outbreak response." FSIS, CFSAN and CDC anticipate that as their surveillance technology improves and the food supply becomes increasingly complex, an effective response to foodborne illness outbreaks will depend on "timely communication to consumers regarding symptoms, treatment, prevention, rapid identification of contaminated food products, and



removal of these products from commerce whenever possible.” The agencies will also hold an invitation-only simulation exercise on May 16.

Food and Drug Administration (FDA)

[3] FDA Publishes Final Rule on Claims Linking Soluble Fiber to Reduced Heart Disease

FDA has issued a final [rule](#) to amend regulations authorizing health claims that assert a relationship between the soluble fiber in certain foods and a reduced risk of coronary heart disease (CHD). Effective May 1, 2008, the final rule will exempt from a “low fat” requirement some foods that derive their fat content from whole oat sources. As a result, the amendment “expands the use of this health claim to some whole oat products that are currently ineligible” due to a fat content that exceeds acceptable nutrient requirements. Whole oat products that qualify to make the health claim cannot “contain any fat from sources other than the fat inherent in the whole oat sources,” according to FDA, which enacted the amendments after considering a petition submitted by the Quaker Oats Co.

[4] FDA Withdraws Guidance for Testing Yellow Corn for StarLink® Residues

Because the Environmental Protection Agency concluded that a bio-engineered corn has been sufficiently removed from the human food supply to render continued testing unnecessary, the FDA has withdrawn its guidance [document](#), “FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues.” The StarLink® corn, which contains Cry9C protein, was created by splicing corn with a gene deadly to the corn borer. It was planted on

limited acreage from 1998 to 2000, and when it was found in U.S. taco shells and other food supplies in Japan, exports to that country were sharply curtailed and steep price drops for all U.S. corn followed. In issue 17 of this Update, we provided details about a preliminary settlement reached by corn farmers and the biotech companies that developed and marketed the bio-engineered corn. The farmers’ lawsuit alleged that Aventis S.A. did not inform farmers that the EPA had approved StarLink® for use in animal feed only, and StarLink® farmers apparently allowed their crops to be mixed with regular corn supplies. *See Federal Register*, April 25, 2008.

Environmental Protection Agency (EPA)

[5] Petition Seeks Regulation of Nano-silver as Pesticide

A coalition of organizations, led by the International Center for Technology Assessment (ICTA), has filed a [petition](#) with the EPA asking the agency to regulate nano-silver, which is used in more than 200 products including food storage containers, “health” drink supplements, food/produce cleaners and cleaning sprays, cutlery, and cutting boards. The nanomaterial at issue is apparently used to kill microorganisms and bacteria. ICTA calls on the EPA “to amend its regulations or otherwise act to clarify that nano-silver is a pesticide and those products incorporating it are pesticide products that must be registered, approved by the agency, and labeled prior to marketing.”

According to ICTA, “[t]he same property that makes these nanomaterials attractive to manufacturers – their highly enhanced antimicrobial action – can be highly destructive to the environment and



raise serious human health concerns. Even in bulk form, silver is toxic to fish, aquatic species and microorganisms and a 2005 study found that nano-silver is approximately 45 times more toxic than standard silver.” ICTA, which is a Washington, D.C.-based non-profit “committed to providing the public with full assessments and analyses of technological impacts on society,” is particularly concerned about nano-silver’s use in food related products that are conducive to “high human exposures” and could contribute to increased bacterial and antibiotic resistance.

The petition seeks the assessment of potential human health and environmental risks of nano-silver under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food Quality Protection Act, the Endangered Species Act, and the National Environmental Policy Act. ICTA asks the agency to take immediate action to prohibit the sale of nano-silver products as illegal pesticide products with unapproved health claim benefits and to impose FIFRA registration requirements on nano-silver products. FIFRA requires EPA to prohibit, condition or allow the manufacture and use of pesticides, and to prescribe conditions for manufacture or use, including ingredient and warning labeling as well as requirements for post-registration notification of adverse impacts.

Litigation

[6] New Bisphenol A Lawsuit Filed in Missouri Against Makers of Baby Products

Alleging that they would not have purchased plastic baby products such as bottles, liners and training cups, had they known the plastic contained bisphenol A, five named plaintiffs have filed a puta-

tive class action in federal court on behalf of a statewide and nationwide class of consumers against several companies that manufacture and sell these products. *Sullivan v. Avent Am., Inc.*, No. 08-309 (U.S. Dist. Ct., W.D. Mo., W. Div., filed April 30, 2008). They seek to recover the amounts spent to purchase the products, the amounts they will spend in the future to replace them and an injunction to prevent defendants from selling products containing bisphenol A in the future without proper labeling. They also seek punitive damages, attorney’s fees and costs.

The complaint cites studies and scientific findings relating to the purported health effects of bisphenol A exposure, including the recent report issued by the National Toxicology Program, and claims that the chemical leaches from defendants’ products at doses that meet or exceed those linked to adverse health effects in laboratory animals. Plaintiffs allege that the defendants subjected them “to unnecessary risks of harm and injury by using a chemical substance, which the defendants either knew to be unsafe or were aware of studies that concluded products made with BPA [bisphenol A], were, at the very least, potentially unsafe and unreasonably dangerous.”

The plaintiffs bring the action on behalf of two classes of purchasers of “plastic baby bottles, bottle liners, nipples, and plastic training cups which were manufactured by defendants and which contained BPA, where the product packaging and labeling did not disclose the fact the product contained BPA and laboratory studies indicate that BPA is associated with health risks.” They acknowledge that the class definitions “may merge into a single national class or into certain sub-classes, the final resolution of which will depend upon the results of discovery.”



The complaint contains counts of intentional and negligent misrepresentation as to both putative classes; as to the Missouri class, the plaintiffs invoke violations of the Missouri Merchandising Practices Act and, as to the national class, the plaintiffs invoke “similar consumer protection statutes of other states, to the extent such statutes afford protection and relief to plaintiffs and the members of the National Class.”

Meanwhile, a putative nationwide class action was filed in another Missouri district court against New Wave Enviro Products, “on behalf of itself and on behalf of a Defendant Class of producers, manufacturers, and/or distributors of polycarbonate plastic bottle products containing the industrial chemical Bishenol-A.” *Hatter v. New Wave Enviro Prods.*, No. 08-3154 (U.S. Dist. Ct., W.D. Mo., S. Div., filed April 30, 3008). The complaint, citing the National Toxicology Program draft brief, contends that the primary source of exposure to bisphenol A for most people is through the diet, in foods and beverages stored in polycarbonate plastic containers and bottles.

The plaintiff alleges violations of the Missouri Merchandising Practices Act, strict products liability for design or manufacturing defect, strict products liability for failure to warn, and breach of implied warranty. She seeks a class certification order, an award of actual damages, injunctive relief, attorney’s fees, and costs. While the complaint contains findings about purported health effects from scientific studies of bisphenol A, plaintiff does not allege any specific existing personal injury from the use of defendant’s products; rather, she simply contends that she and the class members have “suffered significant damages.”

[7] Consumer Class Action Filed Against Tyson for “Raised Without Antibiotics” Ads

Named plaintiffs from California, Florida, Illinois, and New York have filed a putative class action lawsuit against Tyson Foods, Inc. for allegedly advertising its chicken and chicken products falsely as “raised without antibiotics.” *Cohen v. Tyson Foods, Inc.*, No. 08-0366 (U.S. Dist. Ct., E.D. Ark., W. Div., filed April 2, 2008). Alleging that “they would not have purchased Tyson’s chickens or chicken products, or would not have purchased them in the quantities and/or at the prices that they did” had it not been for the company’s deceptive conduct, plaintiffs seek certification of four statewide classes of consumers “who purchased Tyson chicken or chicken products during the relevant time period, having been exposed to Tyson’s false advertising as described herein.”

The complaint alleges unfair and deceptive advertising in violation of the four states’ consumer protection laws and asks for “actual, compensatory, statutory, punitive and/or exemplary damages,” a disgorgement of profits by which the company “was unjustly enriched,” attorney’s fees, and costs. The plaintiffs refer to litigation involving Tyson and its competitors, previously reported in this Update, and recite the history behind U.S. Department of Agriculture approval, revocation and ultimate qualification of Tyson’s marketing claims. A company spokesperson has reportedly characterized the claims as unfounded and indicated that Tyson will “vigorously defend itself.” See *Product Liability Law 360*, April 28, 2008.

In a related development, a federal appeals court has reportedly denied Tyson’s attempt to stay a preliminary injunction issued in the lawsuit filed by its competitors. Accordingly, Tyson must cease



making qualified or unqualified advertising claims that its chicken is raised without antibiotics. See *Associated Press*, May 1, 2008.

[8] Appeals Court Panel Lifts Stay on NYC Menu Posting Rules

The Second Circuit Court of Appeals has reportedly lifted the temporary stay it imposed on New York City's implementation of a new rule requiring chain restaurants to post caloric content information on menus and menu boards. *N.Y. State Rest. Ass'n v. NYC Bd. of Health*, No. 1:08-1000 (U.S. Dist. Ct., S.D.N.Y., order entered April 29, 2008). While no legal impediment now stands in the way of the rule's enforcement, the court's order was apparently premised on the city's agreement to delay issuing fines until mid-July 2008. The court, which has ordered the restaurant association plaintiff to seek an *amicus* brief from the Food and Drug Administration, apparently expects to issue its ruling by then.

Plaintiff has challenged the rule on preemption and constitutional grounds. According to a news source, during the argument on its request for a stay, the plaintiff faced aggressive questioning from the three-judge appeals panel. One judge, who apparently disagreed with the assertion that requiring caloric content wrongly focuses customers on such information, was quoted as saying, "If we were to adopt your view, no warning would appear on anything. There are cigarette warnings and people manage not to look at them. You can rest assured that some people are willfully blind." Claiming that more than one-half of New Yorkers are overweight or obese, the health department has apparently indicated that its regulation will prevent 150,000 from becoming obese and will prevent the development of diabetes and other health problems

in another 30,000 others over the next five years. See *Associated Press* and *Product Liability Law 360*, April 29, 2008; *Reuters*, April 30, 2008.

Other Developments

[9] Industrial Farm Animal Production Commission Releases Final Report

A commission that has studied issues relating to large-scale farm operations for the past two years released its final [report](#) April 29, 2008, claiming that such animal production methods often pose "unacceptable risks" to public health, the environment and the animals themselves. Funded by The Pew Charitable Trusts and Johns Hopkins Bloomberg School of Public Health, the Pew Commission on Industrial Farm Animal Production launched its study in 2006; additional information about the launch appears in issue 185 of this Update. The commission conducted 10 public meetings at which members heard from industry stakeholders and others and also participated in five congressional briefings. Commission members included academics, legislators, ranchers, public health officials, and environmentalists. Among those who served since the commission formed were former agriculture department secretary Dan Glickman and author and food activist Marion Nestle.

According to the executive summary, the commission focused on the effects of "increasing the speed of production" and "the intensive confinement production system." Among those effects were an "increase in the pool of antibiotic-resistant bacteria because of overuse of antibiotics; air quality problems; the contamination of rivers, streams, and coastal waters with concentrated animal waste; animal welfare problems, mainly as a result of the



extremely close quarters in which the animals are housed; and significant shifts in the social structure and economy of many farming regions throughout the country.” The commission contends that industrial farm animal production (IFAP) systems “are largely unregulated.” The report, titled *Putting Meat on the Table: Industrial Farm Animal Production in America*, recommends (i) phasing out and then banning the non-therapeutic use of antimicrobials, (ii) improving disease monitoring and tracking, (iii) regulating IFAPs “as rigorously as other industrial operations,” (iv) phasing out intensive confinement, (v) increasing competition in the livestock market, and (vi) improving animal agriculture research.

[10] TFAH Questions Safety of U.S. Food Supply

Trust for America’s Health (TFAH) this week published a report titled [*Fixing Food Safety: Protecting America’s Food Supply from Farm-to-Fork*](#), which “identifies major gaps in the nation’s food supply system, including obsolete laws, misallocation of resources, and inconsistencies among major food safety agencies.” Summarizing several studies released by the National Academy of Sciences, the Institute of Medicine, the Government Accountability Office, and the Food and Drug Administration, the report points to depleted agency resources in noting that “the bulk of federal food safety funds are spent on outdated practices” which fail to anticipate changing threats such as agroterrorism. TFAH also attributes recent outbreaks of *Salmonella* and *E. coli* to FDA budget and staffing shortfalls, estimating that “85 percent of known foodborne illness outbreaks are associated with foods regulated by [FDA], but the agency receives less than half of the federal funding for food safety.” Furthermore, only 1 percent of imported foods receive inspections at a time when

approximately 60 percent of fresh produce and 75 percent of seafood consumed in the United States is imported, according to the public interest group.

The report thus recommends that government, consumer advocates and industry work together to modernize the food supply using “strategic inspection practices and state-of-the-art surveillance.” In particular, TFAH calls on lawmakers and stakeholders to: (i) “Repeal outdated end-product and processing plant inspection mandates and shift the emphasis of inspection practices to the prevention of outbreaks and illness through the entire food production process and supply chain”; (ii) “Create mechanisms that allow inspection practices to keep pace with changes in the industry”; (iii) “Establish uniform performance standards and best practices that are enforceable through actions including detention and recall authority and civil penalty authority”; (iv) “Require food safety education for commercial handlers”, (v) “Improve monitoring of foreign imports and international practices”; and (vi) “Strengthen the FDA with increased funding and aligning resources with high risk threats, with the long-term goal of realigning all federal food safety functions.” “Our goal should be reducing the number of Americans who get sick from foodborne illness. But we can’t adequately protect people from contaminated foods if we continue to use 100 year-old practices,” the TFAH executive director was quoted as saying. See *TFAH Press Release*, April 30, 2008.

[11] Rising Food Prices and Commodity Shortages Spur Demands for Change

While recent news coverage has reported on widespread riots over food shortages and skyrocketing prices around the world, a number of proposals are being considered to alleviate the



problems. The Oakland Institute, a California-based policy think tank, for example, has issued a policy [brief](#), “Food Price Crisis: A Wake Up Call for Food Sovereignty.” It calls for safety nets to ensure food security for the most vulnerable populations, increased funding to help affected countries develop their own agricultural sectors, a shift away from the free market ideology to allow developing countries to protect their agriculture and ensure the better management of food stocks, and increased support for small, subsistence farmers.

Meanwhile, some in the U.S. Congress are calling for a relaxation of environmental rules, greater acceptance of genetically modified crops and scaling back the renewable fuels standard mandate as measures to counteract rising food prices. House Republicans are reportedly leading the charge to change any rules that have the effect of adversely affecting the agricultural industry, and Senate leadership sources have been quoted as saying, “We will give serious consideration to any honest proposals to bring down food and fuel prices.” *See Reuters*, May 1, 2008; *Inside EPA*, May 2, 2008.

Scientific/Technical Items

[12] Study Finds Diet Choices Affect Environmental Impact More Than Food Miles

A forthcoming [study](#) by Carnegie Mellon researchers has reportedly claimed that diet choices affect a consumer’s environmental impact more than buying local products. C. L. Weber and H. S. Matthews, “Food-Miles and the Relative Climate Impacts of Food Choices in the United States,” *Environmental Science & Technology*, 2008. Christopher Weber and Scott Matthews apparently found that “replacing meat and dairy products once

per week with chicken, fish or vegetables has about the same effect as eating a locally sourced diet,” according to an April 28, 2008, article appearing on *Food Navigator-USA.com*. The researchers assessed the total lifecycle of various food items and nonalcoholic beverages from farm to fork using an input-output method to track the total greenhouse gas (GHG) emissions associated with production, transportation and distribution to U.S. households. Their results ultimately deduced that food production generates more GHG emissions than average transportation routes estimated at 1,640 km for delivery and 6,760 km along the supply chain. “Different food groups exhibit a large range in GHG intensity,” the authors noted. “[On] average, red meat is around 150 percent more GHG intensive than chicken or fish. Thus, we suggest a dietary shift can be a more effective means of lowering an average household’s food-related climate footprint than ‘buying local.’”

Weber and Matthews nevertheless cautioned that their study only examined climate impacts, “which are only one aspect related to food choice,” and that “any attempt to change consumer behavior based on only one dimension of food choice is unlikely to be effective.” As the *Food Navigator* synopsis concludes, however, “the findings are noteworthy for manufacturers and producers looking to market to ethically-minded consumers, or looking to reduce their own carbon footprint.”

[13] Report Links Obesity to Foods Readily Available in Local Communities

The California Center for Public Health Advocacy (CCPHA) has released a [report](#), *Designed for Disease: The Link Between Local Food Environments and Obesity and Diabetes*, which purports to show that “people who live near an



abundance of fast-food restaurants and convenience stores compared to grocery stores and produce vendors, have a significantly higher prevalence of obesity and diabetes regardless of individual or community income.”

According to the researchers, who studied data related to the density of retail food establishments and grocery stores as well as obesity and diabetes rates in California, adults living in high-density retail food environments had a 20 percent higher prevalence of obesity and a 23 percent higher prevalence of diabetes than their counterparts living in lower density environments. They further determined that this relationship “was found to hold true regardless of household income, race/ethnicity, age, gender, or physical activity of the respondents.”

CCPHA recommends that policymakers consider (i) increasing access to healthy foods by providing incentives for retail store development and improvement, (ii) promoting retail innovations, such as smaller-scale markets selling healthy foods, (iii) maximizing opportunities by the changes in the Women, Infant and Children’s food package, (iv) implementing zoning to limit fast-food restaurants in overburdened communities, and (v) requiring menu labeling.



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