Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Releases Draft Safety Assessment of BPA in Food Contact Materials

FDA recently **announced** a meeting of the Science Board's Bisphenol A (BPA) Subcommittee to discuss a **draft assessment** of BPA for use in food contact applications, including epoxy-based food can liners and polycarbonate baby bottles. Slated for September 16, 2008, in Washington, D.C., the meeting will address the draft assessment's finding that trace amounts of BPA leached from food contact materials do not pose a significant risk to adults or infants. The FDA report "particularly focused on the concerns for developmental toxicity identified in recent assessments of BPA, including those of the National Toxicology Program and their expert panel." Estimating that daily BPA exposure from food contact materials for infants and adults is 2.42 μg/kg bw/day and 0.185 μg/kg bw/day, respectively, FDA concluded that "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses." *See Beverage Daily.com*, August 20, 2008.

Meanwhile, several environmental groups have alleged that the assessment is based on industry-funded studies. Although FDA had previously declared the food additive safe, it decided to revisit the issue after the National Toxicology Program registered "some concern" about infant exposure to BPA. Critics of the food contact materials have long alleged that BPA has an adverse effect on human reproductive development and health. "It's ironic FDA would choose to ignore dozens of studies funded by [the National Institutes of Health] – this country's best scientists – and instead rely on flawed studies from the industry," opined Pete Meyers, chief scientist of Environmental Health Studies. *See The Wall Street Journal*, August 15, 2008.

In a related development, Meyers reviewed a recent study published in *Environmental Health Perspectives* that reportedly links BPA in human fat tissues to suppressed "levels of a key hormone, adiponectin, that protects people from heart attacks and Type 2 diabetes." E.R. Hugo, et al., "Bisphenol A at Environmentally Relevant Doses Inhibits Adiponectin Release from Human Adipose Tissue Explants and Adipocytes," *Environmental Health Perspectives*, August 2008. Meyers reported that after treating human fat tissues with BPA, the researchers found that almost all of the samples suppressed adiponectin release despite patients' varying background rates of adiponectin release. "These results show that BPA at levels well-within the range of common human exposure suppresses levels of a hormone that protects people from meta-

bolic syndrome and its consequences: heart disease and Type 2 diabetes," according to Meyers, who noted that the research applied only to adult exposure and warned that "early life stages are usually more vulnerable to endocrine disruption." *See Environmental Health News*, August 2008.

[2] FDA Permits Food Producers to Irradiate Fresh Spinach and Iceberg Lettuce

FDA this week **amended** food safety regulations to permit the irradiation of fresh spinach and iceberg lettuce to eliminate *E. coli* and other pathogens. Effective immediately, the new rule provides "for the safe use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in fresh iceberg lettuce and fresh spinach . . . at a dose up to 4.0 kiloGray (kGY)." FDA announced its decision after concluding that irradiation does not affect the quality of produce or reduce its overall nutritional value. Food producers can already irradiate beef, eggs, poultry, oysters, and spices.

"These irradiated foods are no less safe than others, and the doses are effective in reducing the level of disease-causing mico-organisms," stated Laura Tarantino, director of the Office of Food Additive Safety. The agency first investigated irradiated produce in response to petitions filed by the National Food Processors Association and the Grocery Manufacturers Association, which has characterized the decision as "one of the single most significant food safety actions done for fresh produce in many years."

Consumer advocates, however, have continued to argue that irradiation makes food less nutritious and possibly dangerous. Although irradiated produce will allow those with weakened immune systems to safely consume fresh greens, groups like the Center for Science in the Public Interest (CSPI) have reportedly contended that the new regulation fails to resolve larger issues in food safety. In addition, CSPI has contested an FDA proposal to relax labeling restrictions for irradiated foods. "We are not opposed to the use of irradiation," CSPI Director Caroline Smith DeWaal said. "[But], it's expensive and it doesn't really address the problem at the source." *See Associated Press*, August 21, 2008; *The New York Times*, August 22, 2008.

[3] FDA Issues Final Rule on Health Claims Linking Soluble Fiber to Lower Risk of Coronary Heart Disease

FDA recently issued a **final rule** that adds barley betafiber as an eligible source of beta-glucan soluble fiber for the purpose of making health claims on certain food products. Cargill Inc. petitioned FDA in June 2006 to expand its regulations on soluble fiber and coronary heart disease health claims to include barley betafiber, a concentrated ß-glucan soluble fiber derived from whole grain barley. After reviewing public input, scientific literature and its own data, FDA concluded that barley betafiber lowers serum total and low density lipoprotein (LDL) cholesterol as much as whole oat and barley products, thus reducing the overall risk of coronary heart disease.

The final rule implements without change a February 2008 interim final rule allowing soluble fiber health claims on foods containing barley betafiber that also meet the minimum requirement of 0.75 grams beta-glucan soluble fiber per serving. Under the new rule, such products could be eligible

to bear the claim that, "Diets low in saturated fat and cholesterol that include 3 grams of beta-glucan soluble fiber from barley betafiber may reduce the risk of heart disease. One serving of [insert name of food] provides [insert number] of grams of this soluble fiber." *See Food NavigatorUSA.com*, August 19, 2008.

U.S. Department of Agriculture (USDA)

[4] USDA Announces Meeting of National Advisory Committee on Meat and Poultry Inspection

USDA recently **announced** a public meeting of the National Advisory Committee on Meat and Poultry Inspection (NACMPI) to "review and discuss international equivalence and the approach to verifying the equivalence of foreign food regulatory systems as the means of ensuring the safety of imported food products." Slated for August 27-28, 2008, the meeting will consider four major food safety perspectives: (i) the approach taken by the FDA and Food Safety Inspection Service (FSIS); (ii) the industry perspective; (iii) a consumer approach; and (iv) several approaches advocated by several foreign governments. NACMPI is responsible for advising the secretary of agriculture on both federal and state meat and poultry inspection programs. FSIS will accept comments on the topics discussed at the meeting until September 29.

State and Local Governments

[5] California Legislature Votes Against Bills to Ban PFCs and Bisphenol A in Consumer Products

The California Assembly this week rejected two bills that would have banned perfluorinated compounds (PFCs) in food packaging and bisphenol A in food containers designed for children younger than age 3. The bill seeking to prohibit PFCs (**S.B. 1313**) fell short by five votes and the bisphenol A measure (**S.B. 1713**) was reportedly defeated on a 27 to 31 vote. Sponsored by Senator Carole Migden (D-San Francisco), the BPA bill sought to cap the chemical in baby bottles and cups at 0.1 part per billion starting in 2009. In addition, the bill would have set maximum levels for formula cans, baby food jars and other containers at 0.5 part per billion starting in 2012. The Assembly granted both bills reconsideration, which would allow lawmakers to vote on them again at a later date.

Although environmental groups blamed chemical company and trade association lobbyists for thwarting the bills, several lawmakers noted that the Assembly lacked the expertise to evaluate chemical safety. "Just because you have something that can be toxic doesn't make it toxic," Assemblyman Bob Huff (R-Diamond Bar) was quoted as saying. *See Product Liability Law 360º*, August 12 and 19, 2008; *The Associated Press*, August 18, 2008; *Sacramento Bee*, August 19, 2008.

Litigation

[6] Court Finds Tuna Failure-to-Warn Claims Not Preempted

The Third Circuit Court of Appeals has decided to allow a woman allegedly poisoned by the mercury in canned tuna fish to pursue her failure-to-warn claims against the company that processed and sold the product. ***Fellner v. Tri-Union Seafoods, L.L.C.*, No. 07-1238 (3d Cir., decided August 19, 2008)**. The court determined that the Food and Drug Administration's (FDA's) failure to take formal action regarding such warnings could not be interpreted as the type of agency action that will preempt conflicting state law.

The plaintiff alleged that, from 1999 to 2004, "her diet consisted almost exclusively of Tri-Union's tuna products." She claimed that the products contained methylmercury, and, because of the company's failure to warn about the risks of excessive consumption, she "contracted severe mercury poisoning and suffered extreme physical and emotional injuries." The district court dismissed her claims finding them preempted by federal law.

The only federal "law" pertaining to the claims involved Food and Drug Administration (FDA) advice to women and children about the potential risks of mercury in fish, a document recommending that the FDA initiate enforcement action if the concentration of mercury in fish exceeds 1 ppm, and a 2004 FDA Commissioner letter opining that tuna processors could not comply with federal law and state law if a Proposition 65 lawsuit filed against them in California were successful. The California litigation, instituted by the state's attorney general, accused fish processors of failing to warn consumers about the mercury in their products. It was ultimately dismissed on federal preemption grounds.

Concluding that "the FDA has regulated neither the risk of mercury in tuna nor the permissible warnings regarding that risk in a manner that conflicts with Fellner's lawsuit," and that "informal expressions of policy such as those in the Commissioner's letter" could not amount to "a regime affirmatively proscribing all warnings obligations," the appeals court rejected the district court's analysis and the defendant's implied conflict preemption arguments. The court also ruled that if Fellner's state law-based claim results in imposing a duty to warn, any such warning would not constitute a "misbranding" under federal law. In this regard, the court stated, "Tri-Union's misbranding theory suffers from the same shortcomings as its prior theories: it identifies no regulatory action establishing mercury warnings as misbranding under federal law, and it fails to explain how the regulatory concerns it *has* identified actually conflict with Fellner's lawsuit."

The court concluded, "This is a situation in which the FDA has promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect. Fellner's lawsuit does not conflict with the FDA's 'regulatory scheme' for the risks posed by mercury in fish or the warnings appropriate for that risk because the FDA simply has not regulated the matter. . . . In the final

analysis, this case involves an agency effort to preempt an area of law traditionally within the states' police powers via informal letter, and to do so only after the conduct at issue in this case occurred."

[7] MDL Judge Refuses to Certify Classes in Contaminated Rice Litigation

A federal court in Missouri, presiding over pretrial matters in a number of transferred cases involving claims that genetically modified rice contaminated conventional crops and led to import bans around the world, has denied the plaintiffs' motion for class certification. *In re: Genetically Modified Rice Litig.*, No. MDL 1811 (U.S. Dist. Ct., E.D. Mo., E. Div., order entered August 14, 2008). The plaintiffs proposed certifying five state-specific classes subdivided into classes of (i) rice farmers who suffered a market loss due to the contamination, and (ii) others asserting non-market losses, "including those relating to diminished yield, contamination of seeds, cleaning of farm equipment, and added costs in sorting and testing rice crops."

The court found that common issues did not predominate, primarily because the farmers, who claimed they could establish the value of their losses using a single pricing factor, actually priced their crops in highly variable and individual ways depending on the contracts they entered with their buyers. According to the court, "The claims of the rice producers in this case do not lend themselves to an easy 'mathematical or formulaic calculation.' An accurate, true assessment of any plaintiff's damages requires an extensive inquiry involving the circumstances of that particular plaintiff." The court compared "the wide-spread contamination of U.S. rice" to a "mass accident" tort, "the sort of case that the Advisory Notes to Rule 23 say should rarely be afforded class treatment."

The court also found that the "other losses" subclass was even less amenable to class certification. "This proposed subclass is simply a catch-all class for any plaintiff who claims any kind of injury related to genetically modified rice contamination. . . . The potential claims that might make up this class would be so numerous and so diverse as to make any trial on the merits wholly unworkable." The court declined as well to certify common issues, noting that the permissibility of such an approach remains an open question in the Eighth Circuit and that the approach "would do little if anything to increase the efficiency of this litigation."

Plaintiffs argued that class certification denial would result in hundreds of full-scale trials across five states, all addressing the same issues about the defendant's conduct and the U.S. rice contamination. The court observed that any number of options could resolve the hundreds of cases pending in the MDL. "Lead counsel can propose a collection of 'test cases' to be tried to verdict before deciding how other cases should be handled. This court also has the option of going to trial on the claims of the plaintiffs named in the master consolidated complaint that was filed in this district. The decision not to certify a class does not necessarily mean that there will be hundreds of identical cases separately tried."

[8] Bisphenol A Lawsuits Transferred to MDL Court

The Judicial Panel on Multidistrict Litigation has

ordered the transfer of 14 actions pending in the federal courts of seven states against the makers of plastic baby bottles containing bisphenol A to the Western District of Missouri. ***In re: Bisphenol-A (BPA) Polycarbonate Plastic Prod. Liab. Litig.*, MDL No. 1967 (J.P.M.L., order entered August 13, 2008)**. According to the panel, "these actions involve common questions of fact," and centralization of the matters in Missouri "will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."

The MDL court in Missouri will preside over pretrial matters, including discovery and class certification; if the litigation survives pretrial motions, the cases should be returned to the transferor courts for trial. The panel notes that nine other cases pending in federal courts around the country will be considered as "potential tag-along actions." The bisphenol A lawsuits started appearing on court dockets in April 2008 after the National Toxicology Program released a report about purported health effects of bisphenol A exposure. Details about the lawsuits can be found in issues 259, 260, 262, 263, and 264 of this Update.

[9] Weight Watchers Fails to Stop Litigation Calling Its Snack Foods into Question

A former Weight Watchers group leader has sued the company in federal court alleging that she was fired because she refused to sell the company's snack foods, which, she contends, kill people. *Nathe v. Weight Watchers Int'l, Inc.*, No. 06-cv-04154 (US. Dist. Ct., S.D.N.Y., second amended complaint filed September 27, 2007). Weight Watchers recently let a deadline elapse that would have allowed it to appeal a court ruling keeping the case alive.

Plaintiff Regina Nathe worked for the company from 1986 until she was dismissed in 2005. As the company changed hands and altered its program to require group leaders to sell company-produced foods, Nathe complained that her students could not afford the food and it was "unhealthy"; she was allegedly ridiculed, admonished and demoted by her superiors when she did so. Nathe failed to meet sales quotas and was allegedly subjected to discriminatory employment practices due to her age.

In her complaint, Nathe alleges that the company claims its "dietary objectives" include providing "science-based, weight-loss programs that are safe, healthy, and effective," but "is actively misleading the public and its customers by promoting and selling food products which contain harmful food additives such as trans fat and other saturated fats, high fructose corn syrup and partially hydrogenated oils which are generally considered to be unhealthy and lead to a myriad of health problems including high cholesterol, high blood pressure and heart disease." Nather also alleges, "As a condition of the continued employment of group leaders by defendant, Weight Watchers requires leaders to make material misrepresentations to its clients concerning these products including but not limited to stating that: 'the products will help achieve your weight loss goals'; 'they are healthy and nutritious'; 'are part of a balanced diet'; and 'are a healthy alternative to other snack foods.'"

In addition to her federal and state age discrimination and human rights violation claims, Nathe alleges deceptive acts and practices. She seeks $6 million in compensatory damages, interest, costs, attorney's fees, punitive damages, and a judgment "enjoining the sale of these harmful products." *See Product Liability Law 360*, August 21, 2008.

[10] Advocacy Group Seeks Pesticide Information from EPA

The Natural Resources Defense Council (NRDC) has reportedly filed a lawsuit against the Environmental Protection Agency (EPA) seeking the studies that EPA used in 2003 to approve a pesticide that could allegedly be linked to the disappearance of honeybees in the United States. Filed August 18, 2008, in a federal court in Washington, D.C., the suit alleges that the EPA has failed to respond to NRDC's Freedom of Information Act request for agency records about the toxicity of clothianidin, which belongs to a class of pesticides called neonicotinoids. These pesticides have apparently been blamed for bee deaths in France and Germany, where their use has been suspended. Clothianidin's approval and introduction into the environment in this country purportedly coincided with the "colony collapse disorder" that has led to the disappearance of millions of honeybees. A 2003 EPA fact sheet reportedly says use of clothianidin could result in toxic chronic exposure to honeybees and other pollinators. *See SFGate.com* and *NRDC Press Release*, August 18, 2008.

Legal Literature

[11] Margaret Sova McCabe, "The Battle of the Bulge: Evaluating Law as a Weapon Against Obesity," *Journal of Food Law and Policy*, 2007

Only recently published, this article explores the various legal strategies that have targeted the nation's "obesity crisis," including regulation and agricultural policy, and shows how they have mostly failed to "motivate social change." According to Pierce Law Center Professor of Law Margaret Sova McCabe, changes to the tax code that affect food marketing and availability could be the best way to alter eating habits. "[C]reating financial incentives that change behavioral structures and support consumer choices of healthier eating habits can be successful. Subsidies have long sustained big agribusiness in the over-production of corn, soy, wheat, sugar, and rice." The article also contends that litigation "has actually made the greatest strides in bringing change to food choices in America." Sova McCabe discusses the obesity-related litigation against McDonald's Corp. and notes that "[i]ronically, or perhaps preemptively," the company "was one of the first fast food restaurants to begin adding healthy options to its menu." The article concludes by calling for "the full spectrum of American medicine, education, and law to change nutritional attitudes and health habits."

Other Developments

[12] CSPI Launches Food Dye Initiative; Parents Urged to File Reports Online

The Center for Science in the Public Interest (CSPI), hoping to convince the Food and Drug Administration (FDA) that synthetic dyes should not be used in foods, is calling on parents to file reports online if they believe their children have been affected by food dyes. CSPI "will periodically forward the reports to the FDA, which denies that dyes cause any problems whatsoever. CSPI wants to hear from parents who believe that food dyes impair their children's behavior, as well as parents whose kids' behavior improved when food dyes were eliminated from their diets."

FDA data reportedly show that the consumption of artificial coloring has increased five-fold over the past 30 years. Allergist Benjamin Feingold apparently demonstrated in the 1970s that many of his young patients had fewer tantrums and were more focused at school when artificial food colorings and preservatives were removed from their diets. CSPI filed a petition in June 2008 calling on the FDA to ban Yellow 5 and 6, Red 3 and 40, Blue 1 and 2, Green 3, and Orange B. While food companies have apparently been phasing out the dyes from foods sold in the United Kingdom and Europe, American versions of the same products continue to contain the synthetic substances.

CSPI Executive Director Michael Jacobson claimed, "The food industry won't fix its American foods until the FDA tells them to. Unfortunately, the FDA asserts, on the basis of its misreading of a 25-year-old report, that there is 'no evidence' that dyes affect behavior." *See CSPI Press Release*, August 21, 2009.

[13] TFAH Publishes 2008 Report on Obesity in America

Trust for America's Health (TFAH) this month published its fifth annual edition of ***F as in Fat: How Obesity Policies are Failing in America***, which "tracks trends in obesity-related rates and policies." The 2008 report concludes that adult obesity rates have continued to rise in 37 states, attributing the trend, in part, to "unhealthy values like oversized portions, the popularization of foods with minimum nutritional quality, and the overuse of TV and video games, which encourage physical inactivity." TFAH calls on the federal government to "convene partners from state and local governments, businesses, communities, and schools" to implement the report's key policy recommendations, including: (i) "Investing in effective community-based disease-prevention programs that promote increased physical activity and good nutrition"; (ii) "Improving the nutritional quality of foods available in schools and childcare programs"; (iii) "Increasing the amount and quality of physical education and activity in schools and childcare programs"; (iv) "Increasing access to safe, accessible places for physical activity in communities"; (v) "Improving access to affordable nutritious foods by providing incentives for grocery stores and farmers' markets to locate in underserved communities"; (vi) "Encouraging limits on screen time for children through school-based curricula and media literacy resources"; (vii) "Eliminating the marketing of junk food to kids"; (viii) "Encouraging employers to provide workplace wellness programs"; (ix) "Requiring public and private insurers to provide preventive services, including nutrition counseling for children and adults"; and (x) "Providing people with the information they need about nutrition and activity to make educated decisions, including point-of-purchase information about the nutrition and calorie content of foods." In addition, the report advises the food and beverage industry to reformulate food products, provide additional product information, and work with local communities to improve access to health foods. *See TFAH Press Release*, August 19, 2008.

[14] Advocacy Group Condemns Educational Toys in Kids' Meals

The Campaign for a Commercial-Free Childhood (CCFC) has reportedly condemned several popular chain restaurants that provide educational toys in their children's meals. The consumer group has

publicly criticized establishments such as Chick-fil-A, Wendy's and Burger King for offering games, books and other learning tools in lieu of cross-promotional toys based on movies or TV shows. Although the companies have pointed to a growing consumer demand for socially responsible toy options, CCFC has decried the effort as another marketing ploy. "We don't think that any type of toy should be used to lure kids into fast-food restaurants, even if they call it educational," CCFC Associate Director Josh Golin was quoted as saying. *See The Atlanta Journal-Constitution*, August 15, 2008.

[15] Local British Authorities Contemplate Removing Obese Children from Families

According to a news source, local authorities in the United Kingdom are considering whether to remove grossly overweight children from their homes and place them in care, much as undernourished children are removed. A public health spokesperson for the Local Government Association was quoted as saying, "As the obesity epidemic grows, these tricky cases will keep on cropping up. If parents consistently place their children at risk through bad diet and lack of exercise, is it right that a council should step in to keep the child's health under review?" Council services have apparently been subjected to "an unprecedented amount of pressure" due to the obesity problem, incurring costs for larger crematorium furnaces, specially equipped ambulances with winches and extra-wide stretchers, and larger tables and chairs in schools. While councils have rarely placed young children into care, their members are calling for a national debate and suggest, at a minimum, that social services be provided to the families of overweight children. *See The Times UK*, August 16, 2008.

Scientific/Technical Items

[16] Study Claims Link Between Trace Arsenic Exposure and Type 2 Diabetes

A recent study has reported a link between low-level arsenic exposure and Type 2 diabetes. Ana Navas-Acien, et al., "Arsenic Exposure and Prevalence of Type 2 Diabetes in US Adults," *The Journal of the American Medical Association*, August 20, 2008. Researchers at the John Hopkins Bloomberg School of Public Health analyzed medical tests from 788 adults, finding that those with low arsenic concentrations in their urine had four times the risk of developing Type 2 diabetes compared to patients with even lower arsenic levels. After controlling for nontoxic organic arsenic found in seafood, the study also concluded that people with Type 2 diabetes had 26 percent higher inorganic arsenic levels than adults without diabetes. Inorganic arsenic is an industrial byproduct that can infiltrate municipal drinking water supplies.

The study authors have reportedly noted that further investigation is necessary to confirm the results and establish whether the link between arsenic exposure and Type 2 diabetes is causal. Prior research has apparently hypothesized that arsenic compounds may impair insulin secretion in pancreatic cells, but it is also possible that people with Type 2 diabetes simply excrete more arsenic, according to Molly Kiles, an environmental researcher at the Harvard School of Public Health. "Urinary arsenic reflects exposures from all routes – air, water and food – which makes it difficult to track the actual source of arsenic exposure let along use the results from this study to establish drinking water standards," Kiles was quoted as saying. *See MSNBC.com*, August 19, 2008.

[17] Researchers Allege That Caffeinated Energy Drink Increases Blood Stickiness

The Times Online reports that research in Australia shows that drinking just one popular sugar-free energy drink increased the "stickiness" of the subjects' blood, raising the risk of blood clot formation. The study apparently involved 30 university students in their 20s, who each drank one 250 ml Red Bull and, when tested, showed a cardiovascular profile like an individual with heart disease. The beverage's makers strenuously denied that the drink posed any danger, said it has been proved safe by "numerous scientific studies," and it has never been banned anywhere it is sold.

One of the researchers, who intends to expand the study to verify its results, suggested that those with existing cardiovascular disease consider talking with a physician before drinking such beverages. Other studies have linked energy drinks to increased heart rates and blood pressure levels, and some people have reportedly died after drinking several cans. A Red Bull spokesperson reportedly indicated that the report would be assessed, but that it did "not show effects which would go beyond that of drinking a cup of coffee. Therefore, the reported results were to be expected and lie within the normal physiological range." *See The Times Online*, August 15, 2008.

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