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LEGISLATION, REGULATIONS AND STANDARDS

FDA Extends Compliance Date for Calorie-Disclosure Labeling Rule

Citing stakeholder concerns over insufficient time to achieve appropriate implementation, the U.S. Food and Drug Administration (FDA) has **extended** by one year the compliance date for its controversial menulabeling rule from December 1, 2015, until December 1, 2016. The new requirements apply to restaurants and similar retail food establishments with more than 20 locations, as well as food facilities in movie theaters, amusement parks and other entertainment venues.

According to a statement from FDA Deputy Commissioner Michael Taylor, the agency will continue its ongoing discussions with covered establishments and plans to release draft guidance in August 2015 that answers frequently asked questions about complying with the rule. *See FDA Statement*, July 9, 2015.

FDA Issues Supplement to 2013 Food Code

The U.S. Food and Drug Administration (FDA) has <u>published</u> modifications to the 2013 Food Code based on recommendations made by industry, regulators and other stakeholders during the 2014 Biennial Meeting of the Conference for Food Protection. The Food Code and its Supplement offer the federal agency's best advice for minimizing the risk of food-borne illness in retail and foodservice venues.

Changes to the 2013 iteration of the Code include: (i) clarification of what information should be included in a Hazard Analysis and Critical Control Point Plan required by a regulatory authority; (ii) clarification of the difference between Typhoid Fever and non-typhoidal *Salmonellosis* when reporting illness and the exclusion and restriction of sick food employees; and (iii) expansion of the duties of the "Person in Charge" to include oversight of the routine monitoring of food temperatures during hot and cold holding. FDA plans to issue its next complete revision of the Food Code in 2017. *See FDA Constituent Update*, July 2, 2015.

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

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If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

Vodka Maker to Appeal ASA Ad Ban

Diageo Great Britain Ltd. reportedly plans to **appeal** the U.K. Advertising Standards Authority's (ASA's) decision to ban a Smirnoff® advertisement for allegedly violating the marketing rules for social responsibility in alcohol marketing. Upholding its own complaint, which claimed that the ad in question linked social success to alcohol consumption, ASA found that "the ad's presentation implied that before the visitor asked for an alcoholic drink, the bar was cold and uninviting and that once his drink had been ordered, the bar changed and became livelier and more fun."

Diageo disputed this interpretation, arguing that the TV spot showed the bar "tilting" to filter out the elements that gave it an unwelcoming atmosphere. According to the ruling's summary of Diageo's response, "The tilt acted as a physical division within the ad and where the pretentious items in the first scene were filtered out and the bar now had a warm friendly atmosphere... [I]t was the removal of the pretentiousness from the first scene that was pivotal to the change in the ad, rather than the presence of alcohol."

"We are deeply disappointed by the ASA's conclusion," a Smirnoff® spokesperson was quoted as saying. "We believe the advert clearly showed two scenarios that were separated by a physical change of the bar symbolizing the 'filtering' of unnecessary pretentiousness, and not by presence of alcohol... we will await the decision of the ASA's appeal process." *See Advertising Age*, July 7, 2015.

LITIGATION

Federal Court Invalidates Maui's Ban on GMOs

A Hawaii federal court has ruled that a Maui ban on genetically modified organisms (GMOs) is preempted by the Plant Protection Act and therefore invalid. *Robert Ito Farm, Inc. v. Cnty. of Maui*, No. 14-0582 (D. Haw., order entered June 30, 2015). The decision begins with an introduction clarifying that the court recognizes the importance of the questions of whether GMOs pose risks, noting, "This order is not an attempt by this court to pass judgment on any benefit or detriment posted by [genetic engineering (GE)] activities or GMOs."

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The Maui prohibition on GMO cultivation or propagation passed in November 2014 and supporters of the initiative filed a lawsuit for a declaratory judgment shortly thereafter. Detractors then filed a lawsuit the following day seeking to invalidate the ban. After disposing with preliminary motions filed by a supporter organization, Shaka Movement, the court turned to the issue of preemption. The federal Plant Protection Act governs "noxious weeds" that can damage crops, the court found, and the GMO ban's purpose is to prevent "transgenic contamination" and to protect the integrity of organic and non-GE markets. "The Ordinance seeks to regulate GE crops, such as genetically engineered papayas and bananas, to prevent those crops from 'contaminating' or damaging non-GE papaya and banana crops," the court said. "In other words, the Ordinance inherently considers GE organisms to be 'noxious weeds' and/ or 'plant pests'" as defined in the Plant Protection Act.

"Even if preemption were not express," the court noted, "the Ordinance would still be preempted because it frustrates the purpose of the Plant Protection Act. The ban on GE organisms, some of which are plant pests, causes the Ordinance to run afoul of the Plant Protection Act's purpose of setting a national standard governing the movement of plant pests and noxious weeds in interstate commerce based on sound science."

The court then refused to certify the question of state law preemption to the Hawaii Supreme Court, finding that state law did preempt the ordinance. "In its Noxious Weed Rules, the Hawaii Department of Agriculture has established criteria for noxious weeds based on, among other things, plant reproduction, growth characteristics, detrimental effects, and distribution and spread," the court said. "These statutes and regulations create a comprehensive scheme addressing the same subject matter as the Maui Ordinance. The statutes and regulations reflect the authority of state agencies over the introduction, propagation, inspection, destruction, and control of plants that may harm agriculture, the environment, or the public."

Accordingly, the court held that the GMO ban exceeded Maui County's authority to impose fines and granted summary judgment for the detractor plaintiffs, repeating again that "[n]o portion of this ruling says anything about whether GE organisms are good or bad or about whether the court thinks the substance of the Ordinance would be beneficial to the County."

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Safeway Recall Notification Putative Class Action Paused During Search for New Plaintiffs

Finding a lack of standing, a California federal court has dismissed the named plaintiffs of a putative class action against Safeway alleging that the company should have notified customers who purchased dangerous products through information gathered from its loyalty-card program. *Hensley-Maclean v. Safeway, Inc.*, No. 11-1230 (N.D. Cal., order entered June 29, 2015). Details about the court's refusal to dismiss the case before discovery appear in Issue **398** of this *Update*.

After proceeding through discovery, Safeway apparently learned that none of the plaintiffs had purchased any products subject to Class I recalls, which occur "when there is a reasonable probability that use of the product will cause serious, adverse health consequences or death." The two named plaintiffs had argued that Safeway should have notified them about recalls of Nutter Butter® Sandwich Cookies and Lucerne® eggs, but later examination revealed that their purchases were not part of any Class I recalls. The court then granted the plaintiffs' motion for leave to add two new class representatives who purchased recalled products from Vons, a Safeway subsidiary.

Proposed "All Natural" Class Action Targets Pepsi's Pure Leaf® Iced Tea

A consumer has filed a putative class action against Unilever U.S., PepsiCo and the Pepsi Lipton Tea Partnership alleging that their line of Pure Leaf® Iced Teas are misleadingly labeled as "All Natural" and preservative-free because they contain citric acid, a synthetic ingredient. Ren v. Unilever U.S., Inc., No. 156463/2015 (N.Y. Sup. Ct., filed June 26, 2015). The complaint asserts that Pure Leaf® labels indicate that the products are natural and contain no preservatives despite containing citric acid, which is "industrially manufactured by fermenting certain genetically mutant strains of the black mold fungus, Aspergillus niger." The companies use citric acid as a preservative, the complaint argues, and it disputes the accuracy of a note in the ingredient list explaining that citric acid provides tartness. The plaintiff seeks class certification, declaratory judgments, damages, restitution, an injunction, and attorney's fees for allegations of unjust enrichment, breach of warranties, negligent misrepresentation and violations of the New York General Business Law.

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California Consumers Allege Foster Farms Knowingly Sold Tainted Chicken

Six consumers have filed a lawsuit against Foster Poultry Farms alleging that the company knowingly sold chicken tainted with *Salmonella* that sickened the plaintiffs with salmonellosis syndrome. *Melendez v. Foster Poultry Farms*, No. BC586891 (Cal. Super. Ct., Los Angeles Cnty., filed July 2, 2015). The complaint asserts that Foster Farms refused to issue a recall after it knew of a link between its products and incidents of *Salmonella* infections. Foster Farms "begrudgingly initiated a very limited recall of its tainted chicken on July 12, 2014," the plaintiffs argue, only after the investigators tested a Foster Farms product from a sickened consumer's home and it tested positive for the outbreak strain of *Salmonella*.

The complaint further alleges that Foster Farms promoted the growth of the bacteria by failing to meet operational and food safety standards in the months before the outbreak. The plaintiffs allege strict product liability, negligence and breach of implied warranty and seek damages for pain and suffering, medical and pharmaceutical expenses, travel expenses, lost wages, loss of consortium and other alleged injuries.

Listing ECJ on Cookie Label Misleads About Sugar Content, Putative Class Action Against Whole Foods Alleges

A consumer has filed a proposed class action against Whole Foods Market Group Inc. alleging that the company's Gluten Free All-Natural Nutmeal Raisin Cookies list evaporated cane juice (ECJ) as an ingredient to mislead consumers about the amount of sugar contained in the product. Bryant v. Whole Foods Mkt. Grp. Inc., No. 15-1001 (E.D. Mo., removed to federal court June 25, 2015). The complaint, originally filed in Missouri state court in April, asserts that ECJ should be listed as sugar under the U.S. Food and Drug Administration's (FDA's) rule that food labels use the most common or usual name of an ingredient. According to the April complaint, the plaintiff seeks class certification and damages. The lawsuit joins a wave of litigation against food manufacturers presenting the same argument. Several courts have dismissed the cases without prejudice or granted stays after FDA indicated that it would publish updated guidance about ECJ. Additional details appear in Issue 554 of this Update.

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OTHER DEVELOPMENTS

FOE Report Claims Food Industry Covertly Manipulates Public Discourse

Friends of the Earth (FOE) has <u>released</u> a report claiming that so-called food and agriculture industry front groups use covert tactics to influence the public discourse around agriculture, organic production and sustainability, and genetically modified organisms (GMOs). Titled *Spinning Food: How Food Industry Front Groups and Covert Communications Are Shaping the Story of Food,* the report alleges that these front groups not only co-opt blogs, social media and other seemingly independent platforms to spread PR messages on behalf of industry, but ally with third-party outlets—such as *National Geographic* and *The New York Times*—to create "an echo chamber of industry talking points on anti-GMO labeling, attacks on organic agriculture and a defense of agrochemicals."

"Rather than responding to changing market demands by shifting the way they do business, these companies are trying to preserve market share and win key policy battles by using 'tobaccostyle' PR tactics," opines the report. "While the food industry's use of public relations to shape popular opinion and policy making is not new, the level of spending, the increase in the use of front groups to promote industry messages and the deployment of covert social media tactics to spin the story of food is unprecedented."

JHSPH Report Evaluates Tactics Used to Implement SSB Taxation in Mexico

A Johns Hopkins Bloomberg School of Public Health (JHSPH) <u>report</u> on Mexico's sugar-sweetened beverage (SSB) tax has concluded that "strong advocacy work, scientific evidence, and knowledge of the political context can be important facilitators to policy change that promotes obesity prevention and control." The case study highlights the strategies used by civil society organizations, public interest lobbyists, health and government officials, and other SSB-tax proponents to (i) build coalitions, (ii) persuade legislators to support the initiative, (iii) generate media attention, and (iv) leverage the perspectives of national and international experts. In particular, it notes that successful advocacy campaigns must "understand the political context to capitalize on windows of opportunity."

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"Overall, it is essential that policy proponents know the political context—the system's structure and the needs of political actors—to act on opportunities that could promote public health goals within broader government pursuits and reforms," notes the report. "Regardless of the underlying rationale for the tax in Mexico, advocates were able to get it passed in part because they were aware of the planned political agenda for fiscal reform and they were able to use the government's public presentation of a health rationale to support their primary argument for the tax—to reduce obesity and diabetes."

Food and Beverage Marketing Aimed at Young Children Focus of New Report

California-based law and policy advocacy organization ChangeLab Solutions has <u>issued</u> a voluminous white paper reviewing legal issues surrounding potential strategies to address the marketing of "unhealthy" foods and beverages purportedly directed to children younger than age 5.

The report details various policy considerations with respect to outdoor advertising, broadcast media, digital and print media, childcare settings and schools, government procurement and vending, government property and government sponsorship, land use planning/zoning, retail environments, taxation, and hospital infant-formula giveaways.

Chicago and Allstate Partner to Predict Food Safety Violations

With help from an Allstate Insurance research team, the City of Chicago has reportedly developed a model to predict which food establishments might fail inspections among the more than 15,000 restaurants within the city's jurisdiction. The research teams analyzed nearly 100,000 sanitation inspection reports to create the prediction model, which assesses the likelihood that a food establishment will commit a critical violation.

According to a city **report**, key factors include (i) whether the establishment has a previous critical or serious violation, (ii) the three-day average high temperature, (iii) nearby garbage and sanitation complaints, (iv) nearby burglaries, and (v) the length of time the establishment has been operating. The city tested the model in a double-blind retrodiction of September and October 2014, finding that following its algorithm would have resulted in 69 percent of violations being found

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in the first month compared to the 55 percent that the existing inspection order had yielded. "That is, an additional 37 establishments would have been cited for violations the first month, as opposed to being discovered later, potentially after patrons became ill," the report states. The city has begun using the model to prioritize inspections while continuing a 2013 initiative to track complaints of food poisoning on social media. *See Chicago Tribune*, July 6, 2015.

SCIENTIFIC/TECHNICAL ITEMS

SSB Consumption Allegedly Linked to 184,000 Deaths Annually

Tufts University researchers have purportedly implicated sugar-sweetened beverages (SSBs) in 184,000 deaths worldwide each year after estimating the role of SSB consumption in adiposity-related cardiovascular diseases (CVD), cancers and diabetes. Gitanjali Singh, et al., "Estimated Global, Regional, and National Disease Burdens Related to Sugar-Sweetened Beverage Consumption in 2010," *Circulation*, July 2015. Relying on data from 611,971 individuals surveyed between 1980 and 2010, "along with data on national availability of sugar in 187 countries and other information," the study estimates that SSB consumption allegedly contributed to 133,000 deaths from diabetes, 45,000 deaths from CVD, and 6,450 deaths from cancer. It also notes that among the most populous countries, Mexico had the largest absolute and proportional deaths from SSBs, with proportional mortality reaching 30 percent in Mexican adults younger than age 45.

"The health impact of sugar-sweetened beverage intake on the young is important because younger adults form a large sector of the workforce in many countries, so the economic impact of sugar-sweetened beverage-related deaths and disability in this age group can be significant," said one of the study's authors in a June 29, 2015, press release. "It also raises concerns about the future. If these young people continue to consume high levels as they age, the effects of high consumption will be compounded by the effects of aging, leading to even higher death and disability rates from heart disease and diabetes than we are seeing now."

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ABOUT SHOOK

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

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





CDC Research Focuses on Prevalence of Sodium Intake Reduction Behaviors

The Centers for Disease Control and Prevention (CDC) has published research examining self-reported efforts to reduce sodium intake among U.S. adults in 26 states, the District of Columbia and Puerto Rico. Jing Fang, et al., "Sodium Intake Among U.S. Adults — 26 States, the District of Columbia, and Puerto Rico, 2013," Morbidity and Mortality Weekly Report, July 3, 2015. Based on data from 180,067 participants, the results evidently show that across all locations, "the median prevalence of taking action to reduce sodium intake was 51%," while "the median prevalence of receiving health professional advice to reduce sodium intake was 22%." The study authors also report that the Southern U.S. Census Region had the highest proportion of respondents that took action or received a professional recommendation to reduce sodium intake.

"The data in this report highlight the opportunity to increase the proportion of health care professionals who advise their patients to reduce sodium intake and the proportion of U.S. adults who take action to reduce sodium intake," state the authors. "Health care professionals can make a difference by recommending healthy dietary patterns, such as the Dietary Approaches to Stop Hypertension. By expanding the use of the sodium-related behavior module, states can enhance the ability to evaluate the effects of sodium-reduction campaigns."