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LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Draft Nutrition and Calorie Labeling Guidance for Retail Venues

The U.S. Food and Drug Administration has **issued** draft **guidance** for industry titled "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11." When finalized, the guidance is intended to assist chain establishments with 20 or more locations (e.g., grocery stores, quick service restaurants, pizza delivery outlets, convenience stores, movie theaters, fast food restaurants) comply with menu-labeling requirements for standard menu items, including self-service offerings. *See Federal Register*, September 16, 2015.

NYC Board of Health Approves Salt Warnings for Certain Restaurant Fare

The New York City (NYC) Board of Health has reportedly amended Article 81 of the NYC Health Code to require food items containing more than 2,300 milligrams of sodium to be singled out on menus and menu boards with a salt-shaker icon and an accompanying warning statement. The initiative affects restaurant chains with more than 15 locations nationwide, and the mandated warning must state that the "sodium content of this item is higher than the total daily recommended limit (2,300 mg).

"Many others recognize the important public health impact of excess sodium intake, and I am hopeful that others will follow suit," Health Commissioner Mary Bassett, was quoted as saying.

The warnings will take effect on December 1, 2015, and reportedly apply to about 10 percent of menu selections offered by chain restaurants covered under the amendment. Violators of the regulation will face \$200 fines. *See The New York Times* and *Associated Press*, September 9, 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.

ASA Upholds Complaint Arising from Online Sweepstakes

The U.K. Advertising Standards Authority (ASA) has **upheld** a complaint alleging that an online “instant-win” promotion organized by Kettle Foods Ltd. was misleading because it required participants to register before finding out if they had won a prize. According to ASA, the U.K. Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code) states that “participants in instant-win promotions must get their winnings at once or must know immediately what they have won and how to claim without delay, cost or administrative barriers.”

Kettle Foods reportedly advertised “instant win prizes” on its potato chip packages, which featured a unique code with instructions directing entrants to a website. Before viewing their potential winnings, consumers were asked to provide identifying information, including full name, postal code, telephone number, email address, date of birth, and a chosen password for subsequent visits. As required by law, the company also offered a “no purchase necessary route” for Republic of Ireland (ROI) consumers who could use a “mastercode” once per day to enter the sweepstakes. Because regular participants tended to use the button intended for free-entry customers, Kettle Foods opted to have all users provide geographic information through the same process and then redirect ROI entrants to a different page.

ASA acknowledged these challenges but argued that the promotion should not have been advertised as an “instant win” sweepstakes because the information on the chip packages did not indicate any need to enter consumer information in addition to the code. “We considered that the requirement to register and enter personal details was significant information about how to participate, and that its omission was likely to mislead consumers about the promotion,” concluded ASA. “Because the promotion referred to ‘instant win prizes’ but included delays and an administrative barrier, and because it misleadingly implied that consumers would find out if they had won simply by visiting a website and entering a code, we concluded that the promotion had breached the Code.”



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Liability Issue for Injuries from Naturally Occurring Toxins Sent to Puerto Rico Supreme Court

A federal court in Puerto Rico has certified a question to the territory's supreme court to determine whether a company can be held liable for injuries stemming from the consumption of a species of shrimp that can contain a naturally occurring toxin. *Cabán v. JR Seafood Inc.*, No. 14-1507 (D.P.R., order entered September 11, 2015).

The plaintiff became quadriplegic after eating shrimp tainted with saxitoxin at a restaurant supplied by JR Seafood. He sued JR Seafood for strict liability, arguing that the product was defective. The district court abstained from ruling, holding, "After careful review of the parties' allegations and applicable law, the court finds that this case relies solely on an unsettled issue of Puerto Rico law, as to which this court cannot reasonably predict how the Puerto Rico Supreme Court would rule." It then certified two questions: "Under the principles of product liability, is a supplier/seller strictly liable for the damages caused by human consumption of an extremely poisonous natural toxin found in a shrimp, even if said food product (and its 'defect') are not a result of manufacturing or fabrication process?" and "If the previous question is answered in the affirmative, would it make a difference if the 'defect' of the food product is readily discoverable scientifically or otherwise?"

Court Approves Nearly \$4-Million Settlement in Kashi GMO Case

A Florida federal court has granted preliminary approval of the settlement reached in a class action alleging that Kashi falsely advertised its products as "All Natural" despite containing genetically modified organisms (GMOs). *Eggnatz v. The Kellogg Co.*, No. 12-21678 (S.D. Fla., order entered September 4, 2015). The court certified the class for settlement purposes and approved the \$3.99-million settlement fund and terms of the agreement, which includes the removal of "All Natural" from Kashi products that contain the contested ingredients. The final approval hearing is set for January 2016. Additional details on the settlement appear in Issue [568](#) of this *Update*.



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Brewery Sues Texas Alcoholic Beverage Commission for Right to Sell Six-Packs

Deep Ellum Brewing Co. has filed a lawsuit against the Texas Alcoholic Beverage Commission challenging the constitutionality of Texas Alcohol Beverage Code provisions forbidding brewers from selling their alcohol products on-site for off-premises consumption. *Deep Ellum Brewing Co. v. Tex. Alcoholic Beverage Comm'n*, No. 15-0821 (W.D. Tex, Austin Div., filed September 14, 2015). Dubbing the campaign “Operation Six Pack To Go,” the brewery argues that distilleries, wineries and brewpubs can sell their products in to-go packaging but breweries cannot, resulting in an unconstitutional distinction in the law.

Texas alcohol codes distinguish between manufacturers, distributors and retailers, prohibiting overlapping ownership but creating exceptions for particular conditions, the complaint asserts. One such condition allows manufacturers to act as retailers in certain situations, such as at wineries and brewpubs. Deep Ellum Brewing alleges that because of this provision, it “has lost and continues to lose business (and resulting profits) because it cannot sell its product on-site for off-premises consumption.” The brewery cannot obtain a brewpub license, which would allow for such sales, because its production of 12,500 barrels of beer surpasses the maximum of 10,000 barrels required to obtain the license.

This distinction amounts to equal protection and substantive due process violations, Deep Ellum Brewing argues, by creating an “arbitrary and irrational discrimination” that cannot be defended even at the lowest level of scrutiny, the rational basis test. The brewery seeks declaratory judgment and a permanent injunction against the enforcement of the contested provisions. “We are sorry that legal action is the only way to bring about fairness in an antiquated system that has failed to adapt to the legal, social, and commercial changes of the past 82 years,” John Reardon, owner of Deep Ellum Brewing, said on a crowdfunding website for Operation Six Pack To Go.

Whole Foods’ “Criterion Collection” Wines Infringe Trademark, Video Company Alleges

Video publisher The Criterion Collection has filed a trademark dilution suit against Whole Foods and an alcohol supplier alleging that a line of wines introduced in June 2015 infringed on its name. *The Criterion*

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Collection v. Whole Foods Mkt., No. 15-7132 (S.D.N.Y., filed September 10, 2015). The Criterion Collection has licensed and published classic films with additional “value added” content since 1984, beginning with *Citizen Kane*. “To the consuming public, ‘The Criterion Collection’ has become, over time, broadly associated with technical excellence, artistic value and cultural importance,” the complaint asserts. In 2015, Whole Foods and Winery Exchange, Inc. began selling “Criterion Collection” wine purported to be hand-selected by the grocery chain’s master sommelier, Devon Broglie. The Criterion Collection alleges that this use infringes its trademark under the Lanham Act and New York law and seeks a permanent injunction and damages.

OTHER DEVELOPMENTS

American Egg Board Campaigned Against Just Mayo, Emails Reveal

Weeks after the U.S. Food and Drug Administration (FDA) sent Hampton Creek Foods a letter warning that its Just Mayo is misbranded because it does not contain eggs, emails obtained through the Freedom of Information Act reportedly indicate that the American Egg Board (AEB) and a public relations firm made a concerted effort to remove Just Mayo from the market. The emails reportedly detail the actions the group undertook, including a complaint to FDA, an attempt to convince Whole Foods to stop selling Just Mayo, aid to Unilever in its litigation against Hampton Creek, and payments to food bloggers who post about how “real and sustainable foods, like eggs,” fit into their lifestyles. Details about Unilever’s lawsuit against Hampton Creek appear in Issue [549](#) of this *Update*.

Public health attorney Michele Simon posted the emails on her [blog](#), alleging that AEB likely broke laws during its attempt to quash Hampton Creek. “Checkoff programs like the Egg Board are legally required to stay within the boundaries of advertising, promotion, consumer education, and research,” she wrote in her post. “Specifically not allowed are lobbying activities. The statute says that no funds shall ‘be used for the purpose of influencing government policy or action.’”

Josh Tetrick, head of Hampton Creek, said, “[W]e are calling for a Congressional investigation into what happened, and we’re optimistic that Congress takes us up on that. We are talking to leaders on both sides of the aisle about potentially investigating some of the things that are out there.”

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In response to the allegations, AEB has denied any inappropriate use of resources. A spokesperson reportedly said, “AEB has never used check-off funds for lobbying purposes,” and noted that the emails about blog sponsorships were from 2012 and unrelated to Hampton Creek. Tetrick and Simon also asserted that a now-retired U.S. Department of Agriculture (USDA) official, National Shell Egg Supervisor Roger Glasshoff, assisted in the campaign by suggesting AEB turn to FDA for help, but USDA issued a statement indicating that it found Glasshoff’s actions to be appropriate because he “fielded a call about a regulatory question and simply referred the inquirer to the correct regulatory authority.” *See Inc.*, September 2, 2015; *FoodNavigator-USA*, September 15, 2015.

SCIENTIFIC/TECHNICAL ITEMS

Case-Control Study Examines Bovine Virus Contribution to Breast Cancer Risk

A case-control study has reportedly identified a “significant” association between bovine leukemia virus (BLV) infection and human breast cancer. Gertrude Case Buehring, et al., “Exposure to Bovine Leukemia Virus Is Associated with Breast Cancer: A Case-Control Study,” *PLoS One*, September 2015. After analyzing breast tissue specimens obtained from 239 donors for the presence of BLV, University of California, Berkeley, researchers apparently detected BLV “in the mammary epithelium of 59% of women diagnosed with breast cancer versus 29% of those with no history of breast cancer.” They further suggest that “as many as 37% of breast cancer cases may be attributable to BLV exposure,” with an odds ratio “comparable to that of commonly cited reproductive, hormone, and lifestyle risk factors for non-hereditary (sporadic) breast cancer.”

As explained in a concurrent press release, a 2014 study published in *Emerging Infectious Diseases* confirmed the presence of BLV in humans, though it is currently unknown how the virus passes between species. The study hypothesizes that possible transmission routes could include undercooked beef or raw cow’s milk, but there may also be a longstanding BLV reservoir in the human population due to millennia of cattle domestication.

The researchers note, however, that this case-control study does not prove the virus causes cancer. As the lead author elaborates, “We still need to confirm that the infection with the virus happened before, not

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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.



after, breast cancer developed, and if so, how... Studies done in the 1970s failed to detect evidence of human infection with BLV. The tests we have now are more sensitive, but it was still hard to overturn the established dogma that BLV was not transmissible to humans. As a result, there has been little incentive for the cattle industry to set up procedures to contain the spread of the virus." *See UC Berkeley Press Release, September 15, 2015.*