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LEGISLATION, REGULATIONS AND STANDARDS

FDA Extends Comment Periods for Draft Industry Guidance on Salt Reduction

The U.S. Food and Drug Administration (FDA) has extended the public comment periods for draft guidance "that provides practical, voluntary sodium reduction targets for the food industry." Titled "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods," the guidance sets short- and long-term sodium targets for the following food categories: (i) cheese; (ii) fats, oils and dressings; (iii) fruits, vegetables and legumes; (iv) nuts and seeds; (v) soups; (vi) sauces, gravies, dips, condiments and seasonings; (vii) cereals; (viii) bakery products; (ix) meat and poultry; (x) fish and other seafood; (xi) snacks; (xii) sandwiches; (xiii) mixed ingredient dishes; (xiv) salads; (xv) other combination foods; and (xvi) baby/toddler foods.

The agency will now accept comments pertaining to the food categories and two-year salt reduction goals until October 17, 2016. The comment period for the 10-year targets as well as feedback on technical challenges and innovative solutions to salt reduction will now be accepted until December 2.

Based on consumption data, FDA estimates that these industry measures will reduce the mean population intake to approximately 2,300 milligrams of sodium per day, from 3,400 mg/day. See FDA Constituent *Update,* August 18, 2016.

UK Exchequer Issues Details on Soft Drink Levy, Childhood Obesity Action Plan

Her Majesty's Treasury (HM Treasury) has released the details of a proposed soft-drink levy announced during March 2016 budget talks as part of the U.K. government's childhood obesity action plan.

Slated to take effect in April 2018, the Soft Drinks Industry Levy (SDIL) would affect the manufacturers of added-sugar soft drinks "with total

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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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sugar content of 5 grams or more per 100 millilitres, with a higher rate for drinks with 8 grams or more per 100 millilitres." The levy exempts beverages with no added sugar—including 100-percent fruit juice—as well as alcohol beverages with alcohol content above 0.5-percent alcohol by volume. The SDIL would also apply to imported soft drinks.

HM Treasury has requested comments on the SDIL by October 13, 2016. Among other things, the government seeks evidence and views from respondents about (i) "the types of added-sugar low alcohol products that may be captured by the levy, and the appropriate approach to these products in the levy legislation"; (ii) whether "making the packager or bottler liable for payment of the levy is the least burdensome option for producers of soft drinks"; (iii) "an appropriate production or import level to define a small operator for the purposes of any exemption or relief"; (iv) whether "the proposal to provide an export credit against future levy liability, restricted to direct exports by the producer, is the best overall solution"; and (v) the proposed registration procedures, compliance arrangements and support.

"This is a levy on producers and importers, and not on consumers, and is designed to encourage producers to reduce the amount of sugar in their products and to move consumers towards healthier alternatives," states the childhood obesity action plan. "We have given producers and importers two years to lower the sugar in their drinks so that they won't face the levy if they take action. Many manufacturers have already taken steps to reduce the overall levels of added sugar in their drinks, but the levy will create stronger incentives for action." Additional details about the SDIL appear in Issue 598 of this *Update*.

WTO Rules Against Russia in EU Pork Ban

The World Trade Organization (WTO) has <u>ruled</u> in favor of the European Union in a dispute over Russia's 2014 ban on the import of live pigs, fresh pork and other pig products following cases of African Swine Fever in some EU regions. The ban violated WTO rules on restricting trade based on sanitary and phytosanitary measures, the organization concluded. In an August 19, 2016, <u>press release</u>, the European Commission admitted that many of the products covered by the prohibition continue to be "restricted by a politically motivated ban imposed on EU agri-food products by Russia," but noted that "the panel's findings are of systemic importance, since they remind Russia about its international obligations and the fact that these cannot be arbitrarily ignored." *See EU Press Release*, August 19, 2016.

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LITIGATION

ECJ Suits Proceed Following FDA Guidance

Two lawsuits challenging the inclusion of "evaporated cane juice" (ECJ) on ingredient lists will continue in light of the U.S. Food and Drug Administration's (FDA's) July 2016 nonbinding guidance recommending that "sugar" be listed instead.

A California federal court refused to dismiss a lawsuit against Lifeway Foods alleging its kefir product packaging misled consumers into believing it contained no added sugar by including ECJ in the ingredients list. *Figy v. Lifeway Foods Inc.*, No. 13-4828 (N.D. Cal., order entered August 16, 2016). The court found the plaintiff's claims to be properly pleaded and was not persuaded by Lifeway's argument that the expiration dates on the labels attached to the complaint suggested that the products were purchased after the plaintiff knew what ECJ is because the labels were merely examples of the product packaging rather than the specific products the plaintiff purchased. Details about Lifeway's motion to the court arguing the case is unaffected by FDA's guidance appear in Issue 608 of this *Update*.

The plaintiff against Lifeway is also a plaintiff in a similar lawsuit against Santa Cruz Natural Inc., which allegedly uses ECJ on the list of ingredients in its sodas. *Swearingen v. Santa Cruz Naturals Inc.*, No. 13-4291 (N.D. Cal., order entered August 17, 2016). Santa Cruz argued that the plaintiffs included several products in their complaint that do not list ECJ; agreeing, the court dismissed the claims against those products.

"The Court has some reservations as to whether a reasonable consumer would be misled as regarding added sugars in the Lemonade Soda and Ginger Ale Soda," the court noted. "The ingredients used by Santa Cruz in the Lemonade Soda are listed on the label as: 'sparkling filtered water, organic evaporated cane juice, organic lemon juice concentrate, organic lemon juice, organic natural lemon flavor.' [] The label also reveals that the product contains 35 grams of sugar. [] It is unclear that a reasonable consumer would believe that 35 grams of sugar naturally occurs, as plaintiffs allege, in filtered water, lemon juice, or other lemon flavorings." However, the court declined to dismiss the products from the case, noting that two of the beverages at issue included fruit purees that could potentially contain sugars in the amount listed on the product label.

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Nature's Way "Healthy" Coconut Oil Dispute to Continue

A California federal court has refused to dismiss a consumer's putative class action alleging Nature's Way misrepresents its coconut oil as a healthy alternative to butter, margarine and other cooking oils despite containing higher levels of saturated fat. *Hunter v. Nature's Way Products*, No. 16-0532 (S.D. Cal., order entered August 12, 2016). The court dismissed Nature's Way's argument that it was not making a nutrient content claim, finding that a "Variety of Healthy Uses" phrase on the label was near enough to "representations about 'Non-hydrogenated; No trans fat' and claims regarding medium chain triglyceride content" to plausibly suggest a nutrient content claim. The claim of misrepresentation was plausibly pleaded as well, the court held, but granted Nature's Way's motion to dismiss claims under California's Unfair Competition Law for lack of specificity. The court also refused to find standing to pursue injunctive relief because the plaintiff was unlikely to purchase the product again.

Abbott Labs Organic Formula Claims Preempted, Court Holds

A New York federal court has dismissed a lawsuit against Abbott Laboratories Inc. alleging the company's Similac[®] Advance[®] infant formula is sold as organic but contains ingredients impermissible in organic foods under U.S. Department of Agriculture (USDA) regulations, finding the claims preempted by the Organic Foods Production Act of 1990 (OPFA). *Marentette v. Abbott Labs.*, No. 15-2837 (E.D.N.Y., order entered August 23, 2016).

Both parties acknowledged that the infant formula was certified organic by Quality Assurance International, an organization accredited by USDA to certify organics. The court considered and found persuasive an Eighth Circuit Court of Appeals decision holding that challenges to an accredited certifying agent's decision were preempted by the OFPA while challenges to the underlying facts were not. Agreeing with the circuit court's reasoning, the court "finds that such a challenge is preempted because '[t]o the extent state law permits outside parties, including consumers, to interfere with or second guess the certification process, the state law is an obstacle to the accomplishment of congressional objectives of the OFPA." Accordingly, the court granted Abbott Labs' motion to dismiss the claims. Additional details about the complaint appear in Issue <u>566</u> of this *Update*.

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Probiotic Yogurt Drink Suit Dismissed at Plaintiff's Request

A California federal court has dismissed a lawsuit against Yakult USA at the request of the plaintiff following two denials of class certification and standing for an injunction. *Torrent v. Yakult USA Inc.*, No. 15-0124 (C.D. Cal., S. Div., order entered August 23, 2016). Yakult argued that the court should refuse to grant the dismissal because the plaintiff was seeking to ensure appellate jurisdiction, but the court rejected that logic. "It would be inappropriate for this Court to refuse Plaintiff's voluntary dismissal with prejudice to attempt to force Plaintiff's continued litigation of these claims and preclude [appellate] review," the court found.

The plaintiff previously attempted to obtain standing for an injunction by purchasing Yakult again after the court told him he would be unlikely to purchase the product in the future because he believed the healthful claims of the product to be untrue. Details about the denials of certification and standing for injunctive relief appear in Issues <u>589</u> and <u>597</u> of this *Update*.

Coffee Co. Faces Slack Fill Putative Class Action

A consumer has filed a putative class action against Eight O'Clock Coffee, a subsidiary of Tata Global Beverages, alleging the company sells varieties of coffee in identical bags but fills them to different levels, amounting to impermissible slack fill. *Sorgenti v. Eight O'Clock Coffee Co.*, No. 16-6295 (S.D.N.Y., filed August 9, 2016). The complaint compares Eight O'Clock's "iconic red flexible metallic bag" filled with 12 ounces of its basic coffee product to the "same sized bags" of its Explorations line—including 100% Colombian Peaks, Central Highlands and African Plains varieties—which contain 11 ounces of product. In addition, other product lines contain 11.5 ounces of product but are sold in the same red packaging, the plaintiff alleges.

"As a consequence, consumers are being misled into believing that they are buying a larger volume of Eight O'Clock Coffee's specialty coffee products than is actually contained in the bag," the complaint asserts. "And more significantly, consumers are unwittingly paying substantially more per ounce for the Eight O'Clock Coffee specialty coffee product alternatives, allowing Eight O'Clock Coffee to collect a premium that it is otherwise failing to disclose to consumers." For alleged violations of New York's General Business Law, the plaintiff seeks class certification, damages, an injunction and attorney's fees.

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Izze Drinks Mislead with Preservative-Free and Dietary Guidelines Claims, Consumer Alleges

A consumer has filed a purported class action against PepsiCo and subsidiary Izze Beverage Co. alleging Izze carbonated juice drinks are misleadingly marketed as containing "no preservatives" despite the presence of citric or ascorbic acid. *Lindberg v. PepsiCo Inc.*, No. 16-6569 (S.D.N.Y., filed August 19, 2016). The complaint also challenges Izze's claim that each bottle "delivers two servings of fruit based on [U.S. Department of Agriculture's (USDA's)] 2010 Dietary Guidelines," which is misleading because "the USDA did away with this measure of servings in its 2010 Guidelines precisely because it misleads consumers about how much of various food groups they should eat or drink."

The plaintiff asserts the dietary guidelines claim is also misleading because it "falsely suggests that Izze Sodas contain the nutritional value and health benefits that can be obtained by eating fruit. Whole fruit contains fiber, vitamins, and minerals. Even if Izze Sodas were originally manufactured with real fruit, they no longer contain any of the nutritional value and health benefits that can be obtained by eating whole fruit."

The plaintiff argues that these allegedly misleading statements led her and other consumers to unfairly pay a price premium. She seeks damages, attorney's fees and an order requiring a corrective advertising campaign for allegations of unjust enrichment and violations of New York and California consumer protection laws.

California Consumer Claims Fraud Against Maple Waffle Company

A consumer has filed a putative class action alleging that EN-R-G Foods' Honey Stinger Gluten Free Organic Maple Waffles do not contain maple syrup as implied by the product's name and packaging. *Johnson v. EN-R-G Foods*, No. 6258 (C.D. Cal., filed August 19, 2016). The waffle package features "a prominent image of a maple leaf and maple syrup splashed on the waffle," leading consumers to believe that the product ingredients include maple syrup, the plaintiff asserts. For allegations of fraudulent inducement, unjust enrichment and violations of California law, he seeks class certification, damages, an injunction and attorney's fees.

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Lawsuits Allege Scallops Caused Hepatitis Outbreak in Hawaii

Two consumers have filed lawsuits against Genki Sushi, Koha Foods and Sea Port Products Corp. alleging they distributed contaminated scallops linked to as many as 206 infections of Hepatitis A. *Mauk v. Genki Sushi USA Inc.*, No. 16-1-1573-08 (Haw. Cir. Ct., filed August 16, 2016); *Cuelho v. Genki Sushi USA Inc.*, No. 16-1-1612-08 (Haw. Cir. Ct., filed August 23, 2016). The plaintiff in one case alleges he was infected with Hepatitis A after eating contaminated scallops, began feeling symptoms that day and ultimately required a seven-day stay in the hospital to recover. The second plaintiff, represented by Bill Marler of Marler Clark, consumed allegedly contaminated food at Genki Sushi and received a Hepatitis A vaccine after learning of the potential exposure. Both lawsuits pursue strict product liability and negligence claims against the defendants and seek to represent a class of affected plaintiffs.

OTHER DEVELOPMENTS

AHA Issues Scientific Statement Linking Added Sugars to Cardiovascular Disease in Children

The American Heart Association (AHA) has <u>issued</u> a scientific statement allegedly linking added sugar consumption "at levels far below current consumption levels" to cardiovascular disease risk factors in children. Published in the August 22, 2016, issue of *Circulation*, the statement recommends that children consume less than 25 grams (100 calories or approximately six teaspoons) of added sugar per day, while advocating that children younger than age 2 should avoid added sugars altogether.

After reviewing the latest studies on the topic, the AHA committee apparently identified "strong evidence" backing "the association of added sugars with increased cardiovascular disease risk in children through increase energy intake, increase adiposity, and dyslipidemia." Among other things, the statement finds that "foods and beverages each contribute half of the added sugars in children's diets, 40 g each," and includes soda, fruit-flavored and sports drinks, cakes, and cookies as the top contributors to added sugar in children's diets.

"Importantly, the introduction of added sugars during infancy appears to be particularly harmful and should be avoided," concludes AHA. "Although added sugars can mostly likely be safely consumed in low amounts as part of a healthy diet, little research has been done to establish a threshold between adverse effects and health, making this an important future research topic."

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Meanwhile, the Sugar Association has noted that AHA's recommendations are "vastly different" from those propounded by "both the 2015 Dietary Guidelines for Americans (ages 2 years and up) and the Food and Drug Administration's (FDA) final labeling rule (ages 4 years and up)," which issued a 10-percent of daily caloric intake target for added sugar. "It is one thing to say that evidence supports an association between soft drinks and obesity and disease risk in children, but to say that evidence exists to support a 100 calorie limit of added sugars in 2-18 year olds is simply not factual," states the Sugar Association in an August 24, 2016, press release. "When consumed appropriately, added sugars and a nutrient-rich diet are not mutually exclusive."

Palm Oil Targeted by Consumer Watchdog's Viral Video

Timed to coincide with PepsiCo's limited reintroduction of Crystal Pepsi soft drinks, SumOfUs has <u>launched</u> a viral video campaign to draw attention to its allegations against the palm-oil industry. The video—which spoofs PepsiCo's 1992 Super Bowl spot—has garnered media attention as well as more than 875,000 views on YouTube.

In particular, SumOfUs reportedly claims that PepsiCo's palm-oil policy does not cover Indonesia-based producer, IndoFood. According to Rainforest Action Network's Gemma Tillack, "A nostalgia for rollerblades and fanny packs is fine, but it's crystal clear PepsiCo needs to open its eyes and realize we are no longer in the 1990's and deforestation, wildlife extinction and labor abuses are no longer acceptable costs of doing business." *See Politico.com and Ad Age*, August 9, 2016.

Meanwhile, an August 18 <u>Forbes column</u> authored by Hudson Institute Senior Fellow Hank Cardello argues that food companies and marketers "no longer have the sole power to shape consumer tastes and fuel demand for their products" because "[t]hat power has largely been hijacked by new influencers—public health activists, celebrity nutritionists, politicians, food bloggers—who have their own agendas."

Pointing to "national, well-organized campaigns for new restrictions," such as those advocating sugar-sweetened beverage taxes and labeling for products containing genetically modified organisms, Cardello recommends that companies not only get to know their detractors, but learn to better leverage their corporate social responsibility programs. The article also urges companies to protect their brands by making "children, low-income populations, health-compromised individuals, and any other vulnerable group off limits for products and practices deemed less healthy."

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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.





"For food and beverage companies, capturing consumers' hearts, minds, and spending is only going to get more challenging, especially since a cacophony of unmuted voices is now interrupting their message," concludes Cardello. "But by listening to those other voices and factoring them into decisions about products and marketing practices, food companies can regain some influence on how consumers perceive their products. Only then will they be able to preserve their brand reputations."