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LEGISLATION, REGULATIONS AND STANDARDS

FDA Drafts Industry Guidance for Salt Reduction

The U.S. Food and Drug Administration (FDA) has published draft guidance “that provides practical, voluntary sodium reduction targets for the food industry.”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.

“Our goal is to promote gradual, efficient voluntary reduction of overall sodium content using effective and sustainable strategies that maintain other measures of nutritional quality,” states the agency in its guidance. “The extent and speed of reduction will be different for different products and categories, since the 10-year targets set were designed to allow for flexibility in reformulation based on differences in food categories and products.”

Relying 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. The agency has requested comments pertaining to the food categories and two-year salt reduction goals by August 31, 2016. It has requested comments on the 10-year targets, as well as feedback on technical challenges and innovative solutions to salt reduction, by October 31, 2016. *See Federal Register*, June 2, 2016.

Meanwhile, the agency reportedly denied the Center for Science in the Public Interest’s (CSPI’s) petition for mandatory salt reduction in packaged and processed foods. “We hope that industry will work cooperatively with the FDA and health experts to achieve the proposed reductions, which would benefit the health of all Americans,” said CSPI

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President Michael Jacobson in a June 1 press release. “While this is a voluntary approach as opposed to the mandatory approach we asked for and that the Institute of Medicine endorsed, it provides clear goals by which companies can be held accountable. And, it helps level the playing field for those companies that are already trying to use less salt in their foods.”

The Grocery Manufacturers Association (GMA) also issued a statement on the proposed guidelines in support of further dialogue with FDA. As GMA Chief Science Officer Leon Bruner explains, “Success in cutting sodium consumption will require a holistic approach that includes actions by manufacturers, retailers and restaurants and that addresses consumer behaviors and preferences... Like others inside and outside of government, we believe additional work is needed to determine the acceptable range of sodium intake for optimal health. This evaluation should include research that indicates health risks for people who consume too much sodium as well as health risks from consuming too little sodium.” *See GMA Press Release, June 1, 2016.*

“Anti-Aging” Gin Discontinued After Ad Board Inquiry

Bompas & Parr has reportedly discontinued its “Anti-AGin Gin” after the National Advertising Division requested substantiation for claims that the product was “the alcoholic equivalent of a facial.” The company claimed the product “rejuvenates the skin while you drink” and was meant “for people who want to stay young but don’t want to give up alcohol.” The ingredients—including “drinkable collagen,” chamomile, witch hazel oil and green tea—were advertised as having skin-nourishing or healing properties. The product’s launch was reportedly accompanied by a press release calling it “a cheeky thank you” to Warner Leisure Hotels’ guests “for keeping our hotels fun and young.” The ad board noted that “humor does not diminish an advertiser’s obligation to make truthful and accurate advertising claims.” Bompas & Parr indicated that the product is no longer for sale and will not be reissued. *See Advertising Self-Regulatory Council, May 26, 2016.*

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.

LITIGATION

Parmesan Product Cases Consolidated

The U.S. Judicial Panel on Multidistrict Litigation has consolidated several putative class actions against a number of companies alleging they labeled their grated-parmesan products as “100% Parmesan” despite containing cellulose. *In re 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, MDL No. 2705 (J.P.M.L., transfer order entered June 2, 2016). The consolidated cases include 16 lawsuits and 33 potential tag-along actions filed against Kraft, Target, Albertsons and others in jurisdictions across the country.

The parties petitioned for centralization in the federal courts of Missouri, Minnesota, Pennsylvania and other states, but the court chose the Northern District of Illinois as “a convenient and accessible forum for actions filed throughout the country regarding products sold nationwide.” The parties also disputed whether the cases should be consolidated into a single multi-product MDL or separate MDLs grouped by the product or primary corporate defendant; the court held that “a single, multi-product MDL is necessary to ensure the just and efficient conduct of this litigation. In many situations, we are hesitant to bring together actions involving separate defendants and products, but when, as here, there is significant overlap in the central factual issues, parties, and claims, we find that creation of a single MDL is warranted.”

New York Court Vacates Stay on Salt-Labeling Menu Rule

A New York appeals court has reportedly vacated a February 2016 order that stayed enforcement of New York City’s regulation requiring chain restaurants with more than 15 locations to post warning icons on menus next to items with more than 2,300 milligrams of sodium. The ruling allows enforcement to begin on June 6, 2016, with violators subject to \$200 fines. The National Restaurant Association (NRA) won an emergency stay on February 29, one day before the regulation’s scheduled March 1 enforcement date. Details about the NRA’s lawsuit challenging the regulation appear in Issues [586](#), [595](#) and [596](#) of this *Update*. See *Reuters*, May 26, 2016.

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California Court Certifies Olive Oil Source, “Extra Virgin” Grade Mislabeling Suit

A California state court has certified a class challenging the source and grade of Safeway Inc.’s olive-oil products, which are labeled as “extra virgin” and “Imported from Italy” despite being manufactured from olives grown and pressed outside that country. *Kumar v. Safeway Inc.*, No. RG14726707 (Cal. Super. Ct., Alameda Cnty., order entered May 24, 2016).

The plaintiff proposed two classes: one composed of consumers who purchased the products relying on the “extra virgin” label and another with consumers who relied on the “Imported from Italy” claims. The court assessed the classes in accordance with each requirement—ascertainability, commonality, typicality, adequacy and superiority—and found the plaintiff’s class definitions demonstrably met each standard. “Defendant’s argument that Plaintiff is required to demonstrate that class members have a common understanding of what ‘extra virgin’ means is unsupported by the authorities cited, and is not well taken,” the court noted.

The plaintiff also leads a challenge against Filippo Berio on similar claims. Details about that case appear in Issues [554](#) and [590](#) of this *Update*.

Second Putative Class Action Targets Quaker Oats’ Glyphosate Use

A consumer has filed a putative class action against The Quaker Oats Co. alleging the company misrepresents its oatmeal products as natural and “eco-friendly” despite containing glyphosate, “a potent herbicide that last year was declared a probable human carcinogen by the cancer research arm of the World Health Organization.” *Wheeler v. Quaker Oats Co.*, No. 16-5776 (N.D. Ill., removed to federal court June 1, 2016).

The complaint argues that although “[t]here is nothing unlawful about Quaker Oats’ growing and processing methods,” the company has misled consumers by claiming “that Quaker Oats is something that it is not in order to capitalize on growing consumer demand for healthful, natural products.” The plaintiff asserts that no reasonable consumer would believe that Quaker’s products “contain anything unnatural, or anything other than whole, rolled oats” after seeing Quaker’s packaging and advertising. For allegations of unjust enrichment, breach of warranties and violations of Illinois’ consumer-protection statutes, the plaintiff seeks class certification, a corrective advertising campaign, an injunction, an

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accounting, restitution and damages. A similar suit against Quaker Oats was filed in May 2016 and reported in Issue [603](#) of this *Update*.

CSPI Sues FDA for Inaction on Shellfish Regulation

The Center for Science in the Public Interest (CSPI) has [filed](#) a lawsuit seeking to compel the U.S. Food and Drug Administration (FDA) to act on the organization's 2012 citizen petition seeking establishment of a performance standard for controlling *Vibrio vulnificus*, bacteria responsible for several deaths related to seafood consumption. *Ctr. for Sci. in Pub. Interest v. FDA*, No. 16-0995 (D.D.C., filed May 25, 2016). CSPI argues that FDA has violated the Administrative Procedure Act by delaying its response to CSPI's citizen petition urging the agency "to establish a performance standard of nondetectable for *V. vulnificus* in raw molluscan shellfish" under the Food Safety Modernization Act.

"Every year, people are getting sick and some are dying from what is a completely preventable disease," CSPI Senior Food Safety Attorney David Plunkett said in a May 26, 2016, press release. "For too long the FDA has observed these illnesses and deaths from its perch on the sidelines – leaving matters to state regulators and the industry. And it's clear that that approach has been a public health failure."

SCIENTIFIC/TECHNICAL ITEMS

Prenatal BPA Exposure Allegedly Linked to Childhood Adiposity

A study allegedly linking prenatal bisphenol A (BPA) exposure to increased fat mass index (FMI) in children has suggested that the common plasticizer "contribute[s] to developmental origins of adiposity." Lori A. Hoepner, et al., "[Bisphenol A and Adiposity in an Inner-City Birth Cohort](#)," *Environmental Health Perspectives*, May 2016.

Using data from 369 mother-child pairs enrolled in the Columbia Center for Children's Environmental Health New York City birth cohort, the study authors assessed the urinary BPA of mothers during the third trimester of pregnancy and followed up with their children from birth through age 7.

Their analysis purportedly shows that although "prenatal BPA concentrations were not associated with birth weight," they were "positively associated" with FMI, body fat percentage and waist circumference (WC) at age 7 years. Upon closer examination, prenatal BPA exposure was significantly associated with increased FMI and WC in girls, but

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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.



not boys. As the study further explains, “These results suggest prenatal BPA exposure is associated with overall body fat and central adiposity, accounting for height. However, contrary to our hypotheses, we found that maternal urinary BPA concentrations were not associated with birth weight, childhood BMIZ [body mass index z-score] at ages 5 and 7 years, and Δ BMIZ from age 5 to 7 years.”

“The evidence that prenatal BPA exposure is associated with measures of obesity in children may be an important underlying factor in the obesity epidemic,” said study author Andrew Rundle, co-director of the Obesity Prevention Initiative at the Mailman School of Public Health. “Endocrine disrupting chemicals like BPA may alter the baby’s metabolism and how fat cells are formed early in life.” *See Mailman School Press Release, May 17, 2016.*