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LEGISLATION, REGULATIONS AND STANDARDS

FDA Issues Final Guidance for Compliance with Menu Labeling Rule

The U.S. Food and Drug Administration (FDA) has issued final guidance to help chain establishments with 20 or more locations (e.g., grocery and convenience stores, quick-service and fast-food restaurants, pizza delivery outlets, and movie theaters) comply with menu labeling requirements for standard menu items and self-service offerings under the Federal Food, Drug, and Cosmetic Act.

According to FDA, the final guidance provides "additional examples and new or revised questions and answers on topics such as covered establishments, alcoholic beverages, catered events, mobile vendors, grab-and-go items, and recordkeeping requirements." Enforcement of the menu labeling final rule will begin on May 5, 2017. *See Federal Register*, May 5, 2016.

FDA Survey Finds Nine in 10 Consumers Rely on Food Labeling Claims

The U.S. Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition has published a report finding that 77 percent of surveyed adults use the Nutrition Facts label at least some of the time when buying a food product. Intended to help the agency regulate food and dietary supplement labeling, the 11th edition of the FDA Health and Diet Survey relies on data from 2,480 participants interviewed by telephone or cellphone about their use of nutrition labels and understanding of nutrition claims, purchasing practices and general attitudes toward nutrition and health issues.

The results highlight consumer attitudes about salt reduction, with almost all respondents agreeing "the nation eats more salt than we should." Of these, 50 percent believe individuals are most effective in curbing their own salt consumption, while 25 percent believe the responsibility lies with food manufacturers and retailers, 5 percent with restaurants, and 5 percent with government. The report also finds that (i) "six in ten adults who had seen claims related to fat thought the govern-

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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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ment sets standards about which products are qualified to use the claim," (ii) 16 percent of consumer who used caffeine products "thought they had experienced adverse health effects from these products"; and (iii) "nine in ten adults had heard of *trans* fat or omega 3 fatty acids," but 25 percent of these respondents "could not tell if the fat raises, lowers, or has no relationship with the risk of heart disease."

"Almost nine in ten U.S. adults said they used claims such as 'low in sodium,' 'rich in antioxidants,' 'contains no added sugar,' and 'no sugar added' when buying food products," states the report. "Yet, only one third of adults thought these claims accurately describe the products."

EFSA Warns of Glycerol-Based Contaminants in Vegetable Oils

The European Food Safety Authority's (EFSA's) Panel on Contaminants in the Food Chain (CONTAM) has issued a [scientific opinion](#) assessing the human health risks of free and esterified 3- and 2-monochloropropane-1, 2-diol (MCPD) and glycidyl esters (GE) in food. According to CONTAM, which considered 7,175 occurrence data, "esters of 3- and 2-MCPD and glycidyl esters were found at the highest levels in palm oil/fat, but most vegetable oil/fats contain substantial quantities." The panel warned that these substances—which form when refining vegetable oils at high temperatures—pose potential health concerns "for average consumers of these foods in all young age groups, and for high consumers in all age groups."

"There is sufficient evidence that glycidol is genotoxic and carcinogenic, therefore the CONTAM Panel did not set a safe level for GE," said CONTAM Chair Helles Knutsen in a May 3, 2016, press release. "The exposure to GE of babies consuming solely infant formula is a particular concern as this is up to ten times what would be considered of low concern for public health."

Setting a tolerable daily intake (TDI) of 0.8 micrograms per kilogram of body weight per day ($\mu\text{g}/\text{kg bw}/\text{day}$) for 3-MCPD and its fatty acid esters, the opinion finds that, in addition to palm and vegetable oils, margarine and infant formula, the foods most likely to contribute to 3- and 2-MCPD and glycidol exposure for various age groups included cookies, pastries and cakes, fried or baked potato products, fried or roast meat, and chocolate spreads. Although manufacturer efforts halved the amount of GE in palm oil and fats between 2010 and 2015, CONTAM notes that "estimated average and high exposures to 3-MCPD from both forms for young age groups including adolescents (up to 18 years of age) exceed the TDI and are a potential concern for health."

LITIGATION

SCOTUS Denies Cert. in POM Wonderful Health Claims Case

The U.S. Supreme Court has denied certiorari in a Federal Trade Commission (FTC) lawsuit against POM Wonderful LLC and Roll Global LLC alleging the companies made false or misleading health claims about their pomegranate-derived products. *POM Wonderful LLC v. FTC*, No. 15-525 (U.S., certiorari denied May 2, 2016). The U.S. Court of Appeals for the District of Columbia previously upheld a Commission decision finding POM misled consumers by claiming its products treat, prevent or reduce the risk of heart disease and prostate cancer, with some claims purported to be supported by clinical studies.

“I am pleased that the POM Wonderful case has been brought to a successful conclusion,” FTC Chair Edith Ramirez said in a May 2, 2016, press release. “The outcome of this case makes clear that companies like POM making serious health claims about food and nutritional supplement products must have rigorous scientific evidence to back them up. Consumers deserve no less.”

Dole Facing Government Investigations over *Listeria* Outbreak

Following a *Listeria* outbreak allegedly linked to a Dole Food Co. salad manufacturing plant, the company is reportedly facing investigations by the U.S. Department of Justice (DOJ) and Food and Drug Administration (FDA). Several media outlets have reported that an FDA investigation obtained through a Freedom of Information Act request found Dole knew of nine positive tests for *Listeria* at the plant taken as early as July 2014, more than a year before the company closed the plant. *See The Wall Street Journal*, April 29, 2016.

In response, Dole issued an April 29 statement expressing concerns “about the recent stories in some publications about the FDA’s observation reports. Those FDA reports deal with issues at our plant that we have corrected. We have been working in collaboration with the FDA and other authorities to implement ongoing improved testing, sanitation and procedure enhancements, which have resulted in the recent reopening of our Springfield salad plant,” the statement says. The company further states, “Dole has recently been contacted by the Department of Justice in connection with its own investigation, and we will be similarly cooperating with the DOJ to answer questions and address any concerns.”

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Details about a consumer lawsuit alleging consumption of the salad product caused one person to become comatose appear in Issue [597](#) of this *Update*.

PETA Suit Against Whole Foods Dismissed

A California federal court has dismissed a lawsuit brought by People for the Ethical Treatment of Animals (PETA) alleging Whole Foods Market Inc. misrepresents its meat products as humanely slaughtered with its Global Animal Partnership (GAP) 5-Step[®] Rating System. *PETA v. Whole Foods Mkt. Cal., Inc.*, No. 15-4301 (N.D. Cal., order entered April 26, 2016). Details about the complaint appear in Issue [579](#) of this *Update*, while information about a previous dismissal without prejudice appears in Issue [593](#).

The plaintiffs asserted that Whole Foods' GAP rating system is a "sham" that is not actually enforced and the advertisements do not adequately disclose that 'key animal treatment standards' under the GAP rating 'are no better or marginally better than is the common industry practice,'" according to the court. Whole Foods filed a motion to dismiss the case arguing that the plaintiffs failed to allege misrepresentations or an actionable omission under California law, and the court agreed. "Whole Foods correctly points out that statements such as 'Great-Tasting Meat From Healthy Animals,' and 'Raised Right Tastes Right,' are 'not actionable statements of fact, because they are not quantifiable, objective statements.'" The court concluded the statements were "unspecific and unmeasurable, and therefore constitute puffery."

The plaintiffs also argued that some of Whole Foods' statements, such as "No Cages," were affirmative misrepresentations because they "merely mimic normal industry practices, which is deceptive given that Whole Foods's advertisements create the impression of ensuring superior animal treatment." The court disagreed, noting the statement was not untruthful about Whole Foods' practices. Accordingly, the court granted Whole Foods' motion to dismiss with prejudice.

Proposed Class Action Targets Glyphosate in Quaker Oats as Potential Carcinogen

A consumer has filed a putative class action against The Quaker Oats Co. alleging the company falsely advertises its oatmeal products as "100% natural" because it contains the herbicide glyphosate. *Cooper v. Quaker Oats Co.*, No. 16-2364 (N.D. Cal., San Francisco Div., filed April 29, 2016). The plaintiff argues the cancer-research arm of the World Health

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Organization declared glyphosate—“a potent and *unnatural* biocide” that the company sprays on oats as a drying agent, according to the complaint—to be a “probable human carcinogen” in 2015. The complaint admits the use of glyphosate is legal but asserts that its use in combination with a “100% natural” claim amounts to misrepresentation. For allegations of breach of warranty and violations of California’s consumer-protection statutes, the plaintiff seeks class certification, a compelled corrective advertising campaign, damages, restitution and attorney’s fees.

Fashion Co. Sues Former NFL Player for Use of “Ferragamo”

Salvatore Ferragamo S.p.A. has filed a lawsuit against Ferragamo Winery and Vince Ferragamo, a former Los Angeles Rams and Green Bay Packers quarterback, for trademark infringement and dilution of the “Ferragamo” mark. *Salvatore Ferragamo S.P.A. v. Ferragamo Winery*, No. 16-3313 (S.D.N.Y., filed May 4, 2016). The fashion company asserts that it owns two trademarks to “Ferragamo” for use in connection with wine, which it produces at a Tuscan estate. The former football player owns and operates Ferragamo Winery in California, and the complaint argues that he and his company have ignored repeated cease-and-desist demands. Salvatore Ferragamo alleges federal trademark infringement, cybersquatting, trade dress infringement, trademark dilution and unfair competition claims, and it seeks damages, an injunction preventing further use of “Ferragamo” in regard to wine production and an order directing the winery to destroy infringing products.

Pickled Cucumbers with Citric Acid Are Not Preservative-Free, Lawsuit Alleges

A consumer has filed a putative class action against Kimlan Foods U.S.A. alleging the company misrepresents its jarred preserved-food products as having “No Preservatives Added” despite containing citric acid. *Hu v. Golden Orchid, Ltd.*, No. 16-2234 (E.D.N.Y., filed May 4, 2016). The plaintiff purchased a 14-ounce jar of pickled cucumbers at a supermarket in New York, allegedly relying on the “No Preservatives” claims when choosing the product, then later discovered that citric acid is “a non-natural, highly chemically processed ingredient regularly used as a preservative (due to its acidic pH level which creates an environment where bacteria cannot thrive) in ready-to-drink tea products.” The complaint further argues that although “the acidic pH of citric acid would most certainly provide tartness to the Products, such explanation is pretextual because the real function of the citric acid in the Products is as a preservative.” For alleged violations of New York consumer-protection

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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.



laws, negligent misrepresentation, unjust enrichment and breach of warranty, the plaintiff seeks class certification, damages, restitution, an injunction and attorney's fees.

OTHER DEVELOPMENTS

U.S. Food System's Impact on Public Health Focus of Georgetown Law Event

Government agency leaders, industry representatives, academics and public health advocates will gather in Washington, D.C., on June 3 for "Vote Food 2016: Better Food, Better Health." Organized by the O'Neill Institute for National and Global Health Law at the Georgetown University Law Center, event sessions will target the next president's food agenda, antibiotic resistance in livestock, sugar and obesity, and food insecurity, with the overarching goal of generating a "clear articulation of the range of legal and regulatory solutions [to health issues] available to whoever is elected in 2016." The O'Neill Institute will later publish the conference proceedings and a related white paper.