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LEGISLATION, REGULATIONS AND STANDARDS

FDA Extends Comment Period for Proposed Rule Addressing Fermented and Hydrolyzed Foods with Gluten-Free Claims

The U.S. Food and Drug Administration (FDA) has extended from February 16 to February 22, 2016, the comment period regarding requirements for fermented and hydrolyzed foods or those containing fermented or hydrolyzed ingredients that carry the “gluten-free” claim. The proposed rule would apply to foods such as sauerkraut, yogurt, pickles, cheese, green olives, vinegar, and FDA-regulated beers.

Intended to address the uncertainty of interpreting test methods in terms of intact gluten, the finalized rule would mandate manufacturers to maintain records demonstrating: (i) “the food meets the requirements of the gluten-free labeling final rule prior to fermentation or hydrolysis”; (ii) “the manufacturer has adequately evaluated its process for any potential gluten cross-contact”; and (iii) “where a potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.” The agency also intends to evaluate the compliance of distilled foods by using scientifically valid methods to determine the absence of protein or protein fragments. *See Federal Register*, January 22, 2016.

CSPI Report Calls for FDA Action on Food Dyes

The Center for Science in the Public Interest (CSPI) has published a report criticizing the U.S. Food and Drug Administration’s (FDA’s) lack of action on food dyes. Titled *Seeing Red: Time for Action on Food Dyes*, the report points to studies allegedly linking food-dye consumption to behavioral issues in children—particularly those diagnosed with Attention Deficit/Hyperactivity Disorder (ADHD)—concluding that FDA “has failed to protect or even inform consumers of the risks of dyes to children.”

“We estimate that over half a million children in the United States suffer adverse behavioral reactions after ingesting food dyes, with an estimated

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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.

For additional information about Shook's capabilities, please contact



Mark Anstoetter
816.474.6550
manstoetter@shb.com



Madeleine McDonough
816.474.6550
202.783.8400
mmcdonough@shb.com

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.

cost exceeding \$5 billion per year, using information cited by the U.S. Centers for Disease Control and Prevention and a recent meta-analysis sponsored by an arm of the food industry," states CSPI. "A study of food labels in one supermarket found that more than 90 percent of child oriented candies, fruit-flavored snacks, and drink mixes and powders are artificially colored."

Claiming that children's exposure to food dyes is higher than initially reported, CSPI asks FDA to require warning labels on products containing food dyes while the agency works to "revoke approvals for all food dyes." In particular, the consumer group opines that FDA erroneously directed the Food Advisory Committee (FAC) in a 2011 meeting to consider whether the available evidence established a causal relationship between food dyes and hyperactivity—"a difficult scientific question to answer, and one that is unnecessary, given the requirement that dyes meet the federal safety standard for color additives."

"Had FDA asked the committee to vote on whether food dyes were safe under the law—i.e., if there were 'convincing evidence that establishes, with reasonable certainty, that no harm will result' from food dyes—it seems likely that the FAC would have voted no," argues CSPI. "Importantly, the FDA also asked the FAC to assess whether dyes certified in the United States affect children in the general population, but did not ask whether dyes affect sensitive subpopulations of children, such as those with behavioral problems or dietary sensitivities, which has been the focus of almost all of the research."

GIPSA Seeks Industry Input on Marketing Grains and Related Commodities

The Grain Inspection, Packers and Stockyards Administration (GIPSA) has requested public comments on the services provided to support "the marketing of grain and related commodities." The agency seeks input from producers, handlers, processors, food manufacturers, exporters, importers, and other industry stakeholders to determine how GIPSA "can best facilitate the marketing of grains, oilseeds, rice, pulses, and related products or products made from them, including co-products of ethanol production, commonly referred to as distillers' grains, based on market-identified quality attributes."

In particular, GIPSA asks respondents to consider the following questions: (i) "Are there any market-identified quality attributes that GIPSA does not currently describe (or provide testing) that would facilitate the marketing of grain, oilseeds, and related products?"; (ii) "What

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role should GIPSA take, if any, in standardizing the testing of inputs and outputs of ethanol coproduct processing?"; and (iii) "Are there any other services that GIPSA could offer to facilitate the marketing of grain, oilseeds, or related products?" The agency will accept written or electronic comments before April 18, 2016. *See Federal Register*, January 19, 2016.

LITIGATION

SCOTUS Decides Class-Action Settlement Offer Issue

The U.S. Supreme Court has held that a class action can continue after the defendant offers the lead plaintiff everything requested and the plaintiff rejects the offer. *Campbell-Ewald Co. v. Jose Gomez*, No. 14-857 (U.S., order entered January 20, 2016). The claim at issue stemmed from an alleged violation of the Telephone Consumer Protection Act by Campbell-Ewald Co. after the U.S. Navy contracted the company to create a multimedia recruiting campaign. Campbell-Ewald offered the plaintiff costs plus \$1,503 per unwanted text message received, but the plaintiff let the settlement offer expire without response. The company then moved to dismiss the case on the grounds that no case or controversy existed because its offer had mooted the plaintiff's claim by providing him with complete relief. The district court denied the motion's argument and the Ninth Circuit later agreed, but other federal appeals courts had decided the issue differently.

The Supreme Court sided with the Ninth Circuit's decision, finding that "an unaccepted settlement offer has no force. Like other unaccepted contract offers, it creates no lasting right or obligation. With the offer off the table, and the defendant's continuing denial of liability, adversity between the parties persists."

Shook, Hardy & Bacon Partner Victor Schwartz spoke to *Law360* about the decision, suggesting the issue as a whole remains to be decided. "The significance of this decision is that it postpones for a later day the key question of whether a defendant's complete offer and payment to a plaintiff can moot a case so that it is no longer a 'case' or 'controversy' under Article III of the U.S. Constitution. Neither the majority nor dissent directly addresses the issue of whether a full offer and tender to a lead plaintiff can moot a class action," he said. Schwartz found persuasive Chief Justice John Roberts' observation in his dissent that "the majority's holding will allow future plaintiffs to have a day in court when there is no reason to do so."

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Government Intervention Pauses Tuna Price-Fixing Lawsuit

The U.S. Department of Justice (DOJ) has intervened in an ongoing series of lawsuits against Tri-Union Seafoods, StarKist and Bumble Bee Foods alleging the companies conspired to set prices for tuna in the United States. *In re Packaged Seafood Prods. Antitrust Litig.*, 15-2670 (S.D. Cal., order entered January 20, 2015). A California federal court granted the government's unopposed motion to intervene at a status conference with attorneys representing several consumer and competitor plaintiffs in the consolidated action. The court found "common questions of law and fact between this civil action and an ongoing criminal grand jury investigation" conducted by the DOJ and accordingly granted a stay in the case. Details about the consolidation appear in Issue [588](#) of this *Update* and additional information on lawsuits brought by grocers appears in Issues [574](#) and [590](#).

Costco Shrimp Case Dismissed for Lack of Standing

A California federal court has dismissed a lawsuit against Costco Wholesale Corp. alleging the company's shrimp was falsely advertised as adherent to a supplier code of conduct on human rights while the product was allegedly obtained through the use of slave labor. *Sud v. Costco Wholesale Corp.*, No. 15-3783 (N.D. Cal., order entered January 15, 2016). The plaintiff argued that she was harmed because she purchased shrimp relying on Costco's misrepresentation; the court disagreed after Costco provided records of the plaintiff's and her mother's purchases, which the company tracks through its membership program. Accordingly the court granted Costco's motion to dismiss but allowed the plaintiff leave to amend. Details about the August 2015 complaint appear in Issue [576](#) of this *Update*.

Whole Foods Reaches Deal in Price-Labeling Suit

Whole Foods and a consumer have reached an agreement in a lawsuit alleging the company misrepresented the prices of its products before the point of purchase. *Burgos v. Whole Foods Mkt. Grp.*, No. 15-7357 (stipulation filed January 20, 2016). The plaintiff alleged that some of Whole Foods' price displays failed to meet the state's requirements, which she argued amounted to violations of New Jersey's consumer-protection statute. The stipulation specifies that the individual plaintiff's claims are dismissed with prejudice, but the plaintiff's proposed class is not bound to the terms of the agreement.



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Jury Holds Peanut Co. Liable for Employee's Peanut Dust Inhalation

A jury in Alabama has found Golden Peanut Co. liable for an accident causing an employee welder to inhale peanut dust, resulting in a pneumonia infection and subsequent lung transplant. *Smith v. Golden Peanut Co.*, No. 14-0999 (M.D. Ala., jury verdict filed January 15, 2015). The welder was apparently inside a grain elevator when a truck began dumping peanuts into the shaft, causing the peanut dust to become “so thick in the work area of the elevator pit shaft that [the welder] could not see his hand in front of his face.” He was then diagnosed with pneumonia, required the use of an oxygen tank and became unable to work. In its verdict, the jury concluded the welder could recover \$718,113.25 for his negligence claim. See Law360, January 15, 2016.

OTHER DEVELOPMENTS

Pacific Standard Profiles Former Dentist Fighting Sugar-Industry Involvement in Government Health Standards

Pacific Standard has [profiled](#) Cristin Kearns, a former dentist who has partnered with journalist Gary Taubes and researcher Stanton Glantz to fight sugar-industry influence on the U.S. government's standards for health and dental care using similar tactics as those Glantz used against cigarette manufacturers in the 1990s. Now a researcher working for Glantz at the University of California, San Francisco, Kearns first became interested in the subject after reading a government-published handout at a dental conference with suggested advice for diabetic patients, including “[i]ncrease fiber, reduce fat, reduce salt, reduce calories,” and it didn't say anything about reducing sugar,” she told the magazine.

Kearns has since reportedly tried to identify where the sugar industry has influenced nutritional science through privately funded studies or roles in policy discussions. “Maybe, for some creative attorney down the road, some of [Kearns'] research or research like that could help in crafting discovery requests,” a staff attorney at the Public Health Law Center at the William Mitchell College of Law told *Pacific Standard*.

Kearns is currently exploring whether industry-funded scientists “published scientific papers that favorably but inaccurately summarized the results of experiments on whether eating too much sugar leads to disease.” She argues that the scientists may have “deliberately muddled the issue,” while Glantz finds them to be “pretty naïve” and blames the “companies and their lawyers and their PR people, who know how to

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manipulate those good values and use them to really stand in the way of the development of knowledge.” See *Pacific Standard*, January 18, 2015.

Details about Kearns’ 2012 article with Taubes appear in Issue [459](#) of this *Update*, while information about the 2015 study conducted with Glantz appears in Issue [558](#).

Global Index Ranks Food Manufacturers’ Responses to Obesity and Undernourishment

The Access to Nutrition Foundation has released its second [Access to Nutrition Index](#)[®] (ATNI), which ranks the 22 largest food and beverage companies on their “contributions to tackling obesity and undernutrition.” According to a concurrent press release, “The 2016 Index concluded that, while some companies have taken positive steps since the last Index, the industry as a whole is moving far too slowly. Scored out of ten on their nutrition-related commitments, practices and levels of disclosure, no company achieved a score of more than 6.4.”

Supported by the Bill & Melinda Gates Foundation, Wellcome Trust and Children’s Investment Fund Foundation, the 2016 Global Index ranks companies in the following areas: (i) governance, including whether the company has a corporate nutrition strategy; (ii) product formulation and nutrient profiling systems; (iii) efforts to make healthier products accessible to consumers via pricing and distribution; (iv) compliance with marketing practices and policies geared toward general consumers and children; (v) workplace health and wellness programs for employees; (vi) product labeling and use of health and nutrition claims, and (vii) engagement with government, policymakers and stakeholders on corporate nutrition policies and nutrition-related issues. Weighting these scores to determine overall performance “in the context of both obesity and diet-related chronic diseases and undernutrition,” ATNI also provides an in-depth profile on each company that identifies individual strengths and areas for improvement.

In addition, the index evaluates four food and beverage manufacturers and two pharmaceutical companies on their compliance with the World Health Organization’s International Code of Marketing of Breast-milk Substitutes (The Code). Taking into account corporate marketing policies and management systems, as well as “in-country” marketing practice assessments, ATNI reports that “none of the six companies’ policies were fully compliant with The Code although there was significant variation in their performance.”

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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.



Based on these findings, ATNI recommends that food and beverage companies not only “tackle obesity by adopting stronger nutrition strategies and policies,” but “address the serious problem of undernutrition in lower-income countries, in spite of the challenges presented by these fragile markets.” Among other things, the report calls on manufacturers to strengthen food labeling and market “more responsibly” to children, in addition to applying their nutrition policies globally—not just in their home markets. ATNI also argues that corporate BMS policies should cover “all types of breast-milk substitutes, including infant formula, complementary foods intended for infants under six months of age, follow-on milk and growing-up milk.”

“Given the global reach of their products, food and beverage companies have a critical role to play in helping to tackle the growing global health crisis caused by poor nutrition,” said Access to Nutrition Foundation Executive Director Inge Kauer. “While companies have a social responsibility to tackle global nutrition challenges, doing so also presents a business opportunity as consumers worldwide demand healthier foods.”