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LEGISLATION, REGULATIONS AND STANDARDS

USDA Issues Compliance Guideline for Labeling of Mechanically Tenderized Beef Products

The U.S. Department of Agriculture’s (USDA’s) Food Safety & Inspection Service (FSIS) has **issued** guidance about new labeling requirements for raw or partially cooked mechanically tenderized beef products, including those injected with marinade or solution. In addition to stating that the products have been mechanically, blade or needle tenderized, the labels must also provide cooking instructions to ensure their proper handling by household consumers, restaurants and similar venues.

Because mechanical tenderization has been linked to the possible introduction of pathogens into the interior of beef products, certain cooking time and temperature combinations can prevent foodborne illness. The labeling mandate takes effect in May 2016 or one year after the new requirements are published in the *Federal Register*. See *USDA Press Release*, May 13, 2015.

FDA Issues Draft Guidance About Mandatory Food Recalls

The U.S. Food and Drug Administration (FDA) has **issued** draft **guidance** about the implementation of mandatory food recall provisions under the Food Safety Modernization Act (FSMA). The guidance provides answers to common questions such as “What evidence might FDA consider when deciding to move forward with a mandatory food recall under Section 423 of the Federal Food, Drug, and Cosmetic Act?” Interested parties may **submit** comments to the Division of Dockets Management until July 6, 2015. See *Federal Register*, May 7, 2015.

California Assembly Committee Rejects Proposed Tax on Sweetened Beverages

A proposed bill (**A.B. 1357**) that would have imposed a 2-cent-per-ounce tax on soft drinks, sweet teas, energy and sports drinks has failed to pass the California Assembly Health Committee by a vote of 10-6.

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“I am disappointed that the committee failed to act today on one of the biggest health crises facing our nation,” said Assemblymember Richard Bloom (D-Santa Monica), author of the legislation. “Diabetes is now the seventh largest cause of death in the nation. If current trends aren’t reversed, one-in-three children born after 2000—and specifically one-in-two African-American or Hispanic children—are expected to develop type 2 diabetes. The overwhelming view of health experts is that the single most significant cause of obesity and diabetes is overconsumption of sugar.”

Revenue generated by the tax would have generated an estimated \$3 billion for health, education and wellness programs aimed at reducing the incidence of obesity, diabetes, cardiovascular and dental disease. The proposal was co-sponsored by the American Heart Association, Latino Coalition for a Healthy California and California Dental Association. *See Associated Press and Press Release of Assemblymember Richard Bloom, May 12, 2015.*

LITIGATION

OFPA Does Not Preempt Putative Class Challenge to “Organic” Labels, Court Finds

A New York federal court has granted in part and denied in part a motion to dismiss a lawsuit alleging that Hain Celestial’s Earth’s Best® food and body-care products are deceptively labeled as “organic,” finding that the Organic Foods Production Act (OFPA) does not preempt the plaintiffs’ claims. *Segedie v. Hain Celestial Grp.*, No. 14-5029 (S.D.N.Y., order entered May 7, 2015). The plaintiffs challenged 69 food products and 20 body-care products labeled “organic,” “natural” or “all natural,” arguing that they contain ingredients inconsistent with the company’s claims.

In assessing precedent on preemption, the court found that a federal agency’s approval of a label does not bar any challenge to that label. The court also determined that the plaintiffs’ claims were legally sufficient as to both the “organic” and “natural” challenges. Hain argued that the ingredients in question were subject to an exemption under OFPA because they were nutrient vitamins or minerals, but the court found no evidence to support the argument and allowed the “organic” claim to proceed.

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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Hain also argued that the plaintiffs failed to establish a definition of “natural” upon which they based their claims, but the court disagreed, finding that the pled definition was appropriate for the motion-to-dismiss stage of litigation. “[I]t is enough that Plaintiffs allege that ‘natural’ communicates the absence of synthetic ingredients. [] Likewise, the [U.S. Food and Drug Administration’s and Department of Agriculture’s] respective policies concerning ‘natural,’ while potentially relevant, are not controlling,” the court said, ultimately allowing the claims to continue. “To be clear, the Court is not establishing a rule of law that foods labeled ‘natural’ may not contain synthetic ingredients—far from it. The alleged presence of synthetic ingredients merely brings the claim of deception into the realm of plausibility.” The court also dismissed several claims, finding no support for the alleged breach of implied warranty, fraudulent concealment or constructive fraud, but several remaining claims were left intact.

Court Dismisses Natural Claims Against Nature’s Own® Wheat Bread

A California federal court has dismissed the claims in a putative class action alleging that Flowers Bakeries misrepresents its Nature’s Own® bread as natural, healthy and wholesome despite containing synthetic ingredients, including azodicarbonamide, the “yoga mat chemical.” *Romero v. Flowers Bakeries*, No. 14-5189 (N.D. Cal., San Jose Div., order entered May 6, 2015).

The plaintiffs argued that the brand name “Nature’s Own,” pictures of “stalks of wheat and pots of honey” and statements such as “no artificial preservatives, colors and flavors” on the packaging of the products misleads consumers into believing that the products are “a natural food product, therefore connoting that [the products] are somehow more healthy and wholesome.”

The court found deficiencies in the plaintiff’s complaint, noting that she failed to clarify which misrepresentation allegations applied to which products. “It is not the task of the Court or of Defendant to diagram the intersection between the challenged products and the mislabeling allegations,” the court said. Accordingly, it dismissed with leave to amend nine claims alleging misrepresentation.

The court then considered whether the plaintiff had standing to challenge products she did not personally purchase, finding preferable the “middle



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ground approach requiring a plaintiff to allege facts establishing that unpurchased products ‘are so substantially similar’ to purchased products ‘as to satisfy Article III requirements.’” Although the products “are of the same kind: bread,” the plaintiff again failed to clarify which allegations applied to each product, so “she essentially invites the Court to pick and choose among them to concoct a workable combination. There is nothing linking the identified products to the alleged misrepresentations, nor anything delimiting the ‘classes’ of products and the misrepresentations to which they pertain.”

Flowers Bakeries also challenged the plaintiff’s standing for an injunction because she is unlikely to purchase the product again. The plaintiff argued that because the company reformulated some of its products, she is likely to be injured again, but the court disagreed, refusing to grant the requested injunction. The court then dismissed most of the claims but granted leave to amend, and it denied Flowers Bakeries’ motion to dismiss based on preemption and primary jurisdiction because the issue could not be fully explored until the plaintiff amended the misrepresentation claims.

Czech Dairy Spread Is Not “Butter,” EU Court Says

The General Court of the European Union has upheld a ruling that pomazánkové máslo, a product primarily marketed in the Czech Republic, cannot be labeled as “butter” under the single common market organization (CMO) regulation. *Czech Republic v. European Commission*, No. T-51/14 (Gen. Ct., order entered May 12, 2015). The product, a spread used in similar ways to butter, has a minimum fat content of 31 percent by weight, a minimum dry nonfat milk-material content of 42 percent, and a water content of up to 58 percent. The court ruled that the product does not meet the regulation’s standards, which require between 80 and 90 percent of milk-fat content, a maximum water content of 16 percent and a maximum dry material content of 2 percent. Further, the court ruled, the Czech Republic cannot circumvent the provisions of the single CMO regulation by claiming to be exempt if the product is not on the exemption list. See *EU Press Release*, May 12, 2015.



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Wisconsin Manufacturer Receives Jail Sentence and \$750,000 Fine over Tainted Cheese

An Illinois federal court has sentenced the former president of a Wisconsin cheese company to five days in jail, one year of probation and a \$750,000 fine for lying to U.S. Food and Drug Administration inspectors about Queso Cincho de Guerrero cheese imported from Mexico and tainted with *E. Coli* and *Salmonella*. *U.S. v. Zurita*, No. 12-cr-0290 (N.D. Ill., sentence entered May 8, 2015).

In 2007, Mexican Cheese Producers, Inc. reportedly received tainted cheese returned by retailers. Company workers apparently scraped and washed the cheese, and it was later resold. No illnesses related to the cheese were reported, and the government could not show that company owner Miguel Leal had ordered the workers' actions, but he pled guilty in 2014 to charges of distributing tainted food and lying about it to federal inspectors. Government prosecutors asked for prison time of 10-16 months. "I don't think I would have put him in custody at all had it not been for deceiving the government," the judge reportedly said. The company's finance and operations manager and a worker who admitted to washing the cheese also received sentences of probation. *See Law360* and *Chicago Sun-Times*, May 8, 2015.

CSPI Threatens Litigation Against Plum Organics and Gerber over Allegedly Deceptive Trade Practices

The Center for Science in the Public Interest (CSPI) has threatened to bring lawsuits against Plum Organics and Gerber Products Co. for allegedly deceptive trade practices in the marketing and labeling of their food products for babies and toddlers. In its May 11, 2015, [letter](#) addressed to Gerber and its parent company Nestle S.A., CSPI notes that the company labels several of its products in the 2nd Foods, 3rd Foods and Graduates lines "as being composed of certain healthful ingredients, when, in fact, the Products contain substantial amounts of other less healthful, less valuable ingredients, such as apple juice, that are not identified at all on the [principal display panel]." Similar allegations appear in the [letter](#) addressed to the heads of Plum Organics concerning the company's baby food and 4 Essential lines.

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The letters assert that both companies market the products as containing high amounts of “healthful, high-value ingredients, such as kale, quinoa, blueberries, and green beans,” when they are mostly composed of “less healthful, less-valuable ingredients, such as apple juice or apple puree” as well as pear juice. “Plum and Gerber are cheating parents financially, and robbing kids nutritionally, with these elaborate bait-and-switch schemes,” CSPI Executive Director Michael Jacobson said in a press release. “If they were actually proud of the major ingredients in their products, wouldn’t they name them on the front of their packages?” The letters warn Gerber and Plum Organics that, should they fail to “resolve their illegal and deceptive advertising” by correctly representing “the presence and proportions” of ingredients on the product labels, CSPI will pursue litigation to seek a permanent injunction and disgorgement of profits. *See CSPI Press Release*, May 12, 2015.

Big Red Takes on Big Ben in Red Cream Soda Trademark Dispute

Big Red, Inc., a beverage company owned by Dr Pepper Snapple Group Inc., has filed a trademark infringement lawsuit against Catawissa Bottling Co., alleging that the company packages its Big Ben cream soda too similarly to Big Red’s red cream soda product. *Big Red, Inc. v. Catawissa Bottling Co., Inc.*, No. 15-1423 (N.D. Tex., filed March 6, 2015). Big Red cites as distinctive its “consistent product packaging, which is unified by a central configuration: Two single syllable words, ‘BIG RED,’ are featured prominently on the center of a label and positioned between stylized text or small accents. The label is then imposed on a clear, wide shouldered bottle with a tapered neck that angles smoothly towards the collar.” Big Ben “is artificially colored to an identical shade of red,” Big Red argues, and “is marketed in product packaging that is nearly identical.” Big Red alleges federal and state trademark and trade dress infringement and dilution, and it seeks an injunction, damages and attorney’s fees.

SCIENTIFIC/TECHNICAL ITEMS

RWJF Study: Industry Takes “Baby Steps” in Curtailing Food Marketing to Children

A study funded by the Robert Wood Johnson Foundation’s Healthy Eating Research Program claims that a decrease in TV food advertisements directed to children is “likely related to a shift in marketing

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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.



tactics” as advertisers “migrate to new media such as Internet-based advergames and social media.” Dale Kunkel, et al., “Evaluating Industry Self-Regulation of Food Marketing to Children,” *American Journal of Preventative Medicine*, May 2015. After conducting a “systemic content analysis of food advertisements appearing in children’s TV programs on the most popular cable and broadcast channels,” the researchers report a decline of 25 percent in the rate at which food ads appeared during children’s programming. They also note a decrease in the use of licensed characters among signatories of the Children’s Food and Beverage Advertising Initiative.

The study opines, however, that the foods and beverages advertised to children still fail to meet stringent nutritional standards. “The lack of significant improvement in the nutritional quality of food marketed to children is likely a result of the weak nutritional standards for defining healthy foods employed by industry, and because a substantial proportion of child-oriented food marketers do not participate in self-regulation,” state the authors, who ultimately recommend government restrictions on food marketing to children. “The lack of success achieved by self-regulation indicates that other policy actions are needed to effectively reduce children’s exposure to obesogenic food advertising.”