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LEGISLATION, REGULATIONS AND STANDARDS

FDA Warning Letter Targets Use of Stevia Leaf

The U.S. Food and Drug Administration (FDA) has published a July 31, 2015, **warning letter** targeting the use of whole stevia leaf in food and beverages. Issued to Ten Ren Tea Co. of San Francisco, Ltd., the letter claims that tea products containing "Stevia leaf, tea bag cut" are adulterated under the Federal Food, Drug, and Cosmetic Act "because they bear or contain an unsafe food additive."

"Any substance added to a conventional food, such as your Ten Ren Chrysanthemum Tea and Hibiscus Spice Tea, must be used in accordance with a food additive regulation, unless the substance is the subject of a prior sanction or is generally recognized as safe (GRAS) among qualified experts for its use in foods [21 CFR 170.30(g)]," notes the agency, which has only permitted highly-refined stevia preparations in specific applications. "[W]e are not aware of any basis to conclude that Stevia leaf is GRAS for use in conventional foods."

In particular, FDA notes that "literature reports have raised safety concerns about the use of such forms of Stevia, including concerns about control of blood sugar, and effects on the reproductive, cardiovascular and renal systems." It also deems the tea products misbranded because "the product labels contain information in a foreign language but do not appear to represent all the required label information in both English and the foreign language."

Senators Question Agencies' Lack of Action on Animal Antibiotic Use

U.S. Sens. Dianne Feinstein (D-Calif.), Kirsten Gillibrand (D-N.Y.) and Elizabeth Warren (D-Mass.) have authored an August 17, 2015, **letter** expressing concern that the U.S. Department of Health and Human Services, U.S. Department of Agriculture and U.S. Department of Defense have not yet responded to an executive order establishing

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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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a Presidential Advisory Council on Combatting Antibiotic-Resistant Bacteria. According to the letter, which claims that food animal production accounts for 75 percent of “medically important antibiotics sold each year,” the appointed agencies have failed to provide a formal response or approve nominations for advisory council members. In particular, the senators ask that the final council include at least three experts from outside the food industry.

“As noted in our December 2014 letter, representatives from industrial animal producers associations and the veterinary drug industry have publically voiced doubts about the need to reduce antibiotic use in animals and about the impact that the [Food and Drug Administration’s] policies will have on the amount of drugs used,” concludes the letter. “However, public health experts agree that the use of antibiotics in animal agriculture is a critical contributor to antibiotic resistance.”

### California Legislation Would Label Food Irrigated with Water from Oil and Gas Field Activities

California Assembly Member Mike Gatto (D-Glendale) has **introduced** a bill (A.B. 14) that would require the labeling of food grown using recycled or treated water from oil and gas field activities.

“No one expects their lettuce to contain heavy chemicals from fracking wastewater,” Gatto said. “Studies show a high possibility that recycled oil field wastewater may still contain dangerous chemicals, even after treatment.”

The proposed label would state: “Produced using recycled or treated oil-field wastewater.” *See Press Release of Assembly Member Mike Gatto, August 17, 2015.*

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## LITIGATION

### Previous *Trans Fat* Litigation Proves Plaintiff’s Knowledge, Court Finds

After dismissing a portion of the claims in July 2015, a California federal court has dismissed the remaining claims in a lawsuit against Nissin Foods Co. Inc. alleging that the use of partially hydrogenated oil (PHO) violates California law. *Guttmann v. Nissin Foods (U.S.A.) Co., Inc., No.*



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15-0567 (N.D. Cal., order entered August 14, 2015). The plaintiff alleged that Nissin sold unsafe food to the public because of the *trans* fat content of its Cup Noodles®. Details of the previous ruling appear in Issue [573](#) of this *Update*.

The plaintiff's claims of unfair business practices and breach of the implied warranty of merchantability rested on his lack of knowledge about the harms of PHO and *trans* fat when he purchased Cup Noodles®. He claimed to believe that the products he purchased were safe to consume when they allegedly were not; however, according to three previous lawsuits against other companies on the same issues, the plaintiff knew of the harms of *trans* fat as early as 2010, leaving the statute of limitations on his claims to expire in 2014. "Guttmann could reasonably have avoided any injury based on Nissin's use of artificial trans-fat by reading the nutrition-facts panel and deciding not to purchase or consume them based on the presence of partially-hydrogenated oil," the court noted, dismissing the remaining claims accordingly.

### General Mills *Trans* Fat Case Stayed for FDA Guidance

A California federal court has granted a stay awaiting guidance from the U.S. Food and Drug Administration (FDA) in a putative class action alleging that General Mills uses partially hydrogenated vegetable oils, which contain *trans* fat, in its baking mixes. *Backus v. Gen. Mills, Inc.*, No. 15-1964 (N.D. Cal., order entered August 18, 2015).

After finding that the plaintiff had standing because he alleged economic and immediate physical injury, the court turned to his claims of unlawful and unfair business practices under California law and held that they were plausibly alleged. The public nuisance and implied warranty of merchantability claims were insufficient, the court found, because the plaintiff failed to show a public harm distinct from his own injury and he failed to allege "that the baking mixes were unfit for even the most basic degree of ordinary use."

The court then granted General Mills' motion to stay the continuing claims under the primary jurisdiction doctrine because it was "clear that the question of whether the amounts of trans fats that were present in General Mills' baking mixes pose a significant safety risk to society is both an important question of first impression, and a complicated

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issue that has been committed to the FDA.” The four factors of primary jurisdiction were all met, the court noted, and further, FDA “explicitly encouraged the food industry to submit petitions for review of trans fats as a food additive, which General Mills has done, through its membership in the Grocery Manufacturers Association. [] This is not a case where the FDA has been silent on the question of whether it will resolve the issue; rather, the FDA set a compliance date for its final order in June of 2018, in order for it to review food additive petitions before that time.”

Details about the complaint appear in Issue [564](#) of this *Update*. The plaintiff has also filed *trans* fat putative class actions against Nestle USA over its coffee creamers and H.J. Heinz Co. over its frozen fries and tater tots. Additional information appears in Issue [569](#) of this *Update*.

### Humane Society’s “Other White Meat” Suit Revived

A lawsuit dismissed in 2013 alleging that the National Pork Board purchased the tagline “The Other White Meat” from the National Pork Producers Council for fraudulent reasons has been revived by the Court of Appeals for the D.C. Circuit. *Humane Soc’y of the U.S. v. Vilsack*, No. 13-5293 (D.C. Cir., order entered August 14, 2015). The lawsuit was initially dismissed because the plaintiffs, including the Humane Society of the United States (HSUS), failed to prove that they had standing to sue. Details of the dismissal appear in Issue [499](#) of this *Update*.

HSUS alleged that the board, a quasi-governmental entity, pays \$3 million annually to license the trademarked phrase from the council, an industry trade group, not because the board intended to market pork with the slogan—which has not been in use since 2011—but rather because it sought to support the council’s lobbying efforts. Upon a *de novo* review, the appeals court found that HSUS’s co-plaintiff, a pork producer, has standing to pursue the claim. “His argument is simple,” the court noted. “He says that his return on his investment has been diminished by the Board’s unlawful payments of \$3 million per year for *Pork: The Other White Meat*. If the Board stopped paying for the slogan, recouped funds unlawfully channeled to the Council, and devoted the money saved to more effective pork promotions, [the plaintiff’s] alleged harm would be at least partially redressed.” The pork producer further showed that the deal was not negotiated at arm’s length, “which increased the plausibility of allegations that the Board paid too much,”

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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.



and that the slogan is no longer worth \$3 million annually. Accordingly, the appeals court reversed the trial court's decision and remanded for further proceedings.

### Costco Shrimp Farmed with Slave Labor, Proposed Class Action Alleges

A consumer has filed a putative class action against Costco Wholesale Corp. alleging that the company sells shrimp obtained with slave labor in Thailand. *Sud v. Costco Wholesale Corp.*, No. 15-3783 (N.D. Cal., filed August 19, 2015). Citing documentaries and media reports, the complaint asserts that through its store brand, Kirkland, Costco has been selling seafood from Thailand "derived from a supply chain that depends upon documented slavery, human trafficking and other illegal labor abuses." Further, Costco "does not advise U.S. consumers, in its packaging or otherwise, that the supply line for farmed prawns has been tainted by the use of slave labor in Thailand, and other nearby locations in international waters, including Indonesia, on Thai-flagged ships, and that there has been no eradication of this plague." Knowingly selling such products and failing to warn the public of the farming conditions allegedly amount to unlawful business practices, misleading and deceptive advertising, and a violation of the Consumer Legal Remedies Act. The plaintiff seeks class certification, an injunction, restitution and costs.

### Fireball® Makers Challenge "Fire Flask" Malt Beverage

Sazerac Co., maker of Fireball® cinnamon whiskey, has filed a trademark infringement action against Stout Brewing Co. alleging that the brewer's Fire Flask displays trademarks and trade dress designed to look like Fireball®. *Sazerac Co., Inc. v. Stout Brewing Co.*, No. 15-0107 (W.D. Ky., Louisville Div., filed August 14, 2015). Fire Flask is a malt-beer product sold in clear bottles with a red cap and a front label featuring an illustration of a "demon-man with flames emanating from his head" in an "orange-yellow, red, and black" color scheme. The Fire Flask mark "is likely to give rise to confusion among consumers as to the source or sponsorship of Defendant's products," the complaint asserts. Sazerac seeks an injunction, corrective advertising, product recalls, an accounting, treble damages, and mark invalidation by the U.S. Patent and Trademark Office.