

ISSUE 738 | March 06, 2020



SPOTLIGHT

FDA Warning Letters Provide Opportunity for Food-Safety Reminders During Viral and Bacterial Outbreaks

By Partner Lindsey Heinz and Associate Zac Parker

The U.S. Food and Drug Administration (FDA) sent warning letters to Jimmy John's Franchise, LLC and its supplier Sprouts <u>Unlimited Inc.</u> regarding food safety practices after the agency traced an outbreak of *E. coli* to Jimmy John's produce, which had previously caused outbreaks of foodborne illnesses. In the letter to Jimmy John's, FDA focused on the company's prior sales of adulterated products, its misrepresentations to FDA regarding the sourcing of its sprouts, and the need for Jimmy John's to demonstrate "long-term, sustainable corrections" that would prevent these outbreaks in the future. It comes as no surprise that letters like these make <u>headlines</u> and risk hurting a food supplier's reputation.

In light of these warning letters and the concerns raised by potential outbreaks of the new coronavirus COVID-19, food manufacturers must be vigilant about supply chain management, whether at the growing, transporting, processing or handling stages. Oftentimes, the supply chain is where adulteration occurs. This process starts with vetting a company's national suppliers and its contracts with them. A few considerations: (i) SHARE WITH TWITTER | LINKEDIN

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contracts should require each supplier to warrant and guarantee that its products and operations are in full compliance with all applicable food safety laws, including those from FDA; (ii) relationships and contracts with suppliers should allow for suspending or stopping purchases when food safety practices need improvement or FDA alleges they need improvement; (iii) documented supplier verification procedures can be used for a fulsome review of a supplier's systems for controlling food safety hazards as well as its compliance with applicable food safety laws; and (iv) companies should consider implementing (or revisiting their implementation of) hazard analysis critical control point (HACCP) principles.

LEGISLATION, REGULATIONS & STANDARDS

FDA Releases Leafy Greens STEC Action Plan

The U.S. Food and Drug Administration has <u>released</u> its plan to combat outbreaks of Shiga toxin-producing *E. coli* (STEC) carried by leafy greens. "Due to the reoccurring nature of outbreaks associated with leafy greens, FDA has developed this commodityspecific action plan," the announcement states. "Expediting the improved safety of leafy greens will require collaboration between FDA and stakeholders in the public and private sectors, including industry and our regulatory partners. This plan is designed to help foster a more urgent, collaborative, and action-oriented approach." The plan details actions on prevention, response and addressing knowledge gaps.

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LITIGATION

Center For Food Safety Challenges Organic Certification For Hydroponic Food

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. The Center for Food Safety (CFS) and several agricultural firms have filed a lawsuit against the U.S. Department of Agriculture (USDA) challenging the agency's denial of the group's petition seeking to ban organic certification of hydroponic food growers. *Ctr. for Food Safety v. Perdue*, No. 20-1537 (N.D. Cal., filed March 2, 2020). USDA denied CFS's <u>January 2019 petition</u>, and CFS argues that the denial was arbitrary and capricious and violates the Organic Foods Production Act (OFPA).

The complaint asserts that USDA ignored the National Organic Standards Board's 2010 recommendation against certifying hydroponic operations as organic and "issued a blanket statement" allowing certification that contradicted the recommendation of the board and a hydroponics task force. "USDA offered no supporting rationale for its statement. USDA made the statement in a website announcement, without any opportunity for public input and without taking any rulemaking action," the plaintiffs argue.

Further, "USDA failed to explain in the Petition Denial how hydroponic operations can meet OFPA's mandatory statutory and regulatory terms that require producers to 'select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion;' 'manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials;' and 'manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances," per the OFPA. CFS seeks declarations that the petition denial violates the OFPA and the Administrative Procedures Act, that USDA "has created an inconsistent organic standard," and that "hydroponic operations do not meet the soil fertility mandates of OFPA" and urges the court to direct USDA "to comply with OFPA by promulgating regulations and otherwise utilizing its authority under OFPA to prohibit organic certification of hydroponic operations."

"Farmstand" Tropicana Contains Malic Acid, Plaintiff Argues

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.

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Two consumers have filed a putative class action alleging that Tropicana misleads consumers by implying that its products are natural despite containing malic acid. Willard v. Tropicana Mfg. Co., No. 20-1501 (N.D. Ill., filed February 28, 2020). The complaint argues that Tropicana "tricks consumers" into buying products by "omitting the legally required disclosures" about artificial flavoring because the juice products list malic acidwhich the plaintiff asserts is the synthetic flavoring form, dl-malic acid—as an ingredient. Tropicana "intended to give reasonable consumers like the Plaintiff the impression that the Products are pure, natural, and not artificially flavored, by packaging, labeling, and advertising the Products" with depictions of fresh fruit and names such as "Farmstand Apple," the plaintiffs assert. For alleged violations of Illinois and California consumer-protection statutes, they seek class certification, injunctions, damages and attorney's fees.

Putative Class Action Alleges Ruffles Chips Contain Artificial Flavor

A plaintiff has alleged that Frito-Lay North America Inc. fails to include a mandated front-of-package disclosure that its Cheddar and Sour Cream chips are flavored with artificial flavoring. *Ithier v. Frito-Lay N. Am. Inc.*, No. 20-1810 (S.D.N.Y., filed March 1, 2020). The complaint asserts that "[b]ased on flavor composition analysis of the Products, the artificial flavor consists of compounds associated with butter flavor," and "butter flavor is known as enhancing and boosting the flavor of cheddar cheese." Thus, according to the plaintiff, the flavor of the chips should be listed as "Artificially Flavored Cheddar & Sour Cream." The plaintiff alleges fraud, unjust enrichment, negligent misrepresentation, breach of warranties and a violation of New York's consumer-protection statute, and he seeks class certification, injunctive relief, damages and attorney's fees. The choice of a lawyer is an important decision and should not be based solely upon advertisements.

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