

# FDA Warning Letter Reminds Restaurants and Franchisors that FDA Expects Best Practices for Food Safety

February 27, 2020 Deborah Coldwell, Maral Kilejian, Robert Lauer, Suzie Trigg

**PRACTICES** FDA Regulatory and Compliance, Food, Beverage and Restaurant, Franchise and Distribution, Franchise Litigation

Food safety issues can grab headlines and leave a restaurant chain's reputation and goodwill vulnerable if not handled correctly. This week, a widely publicized warning letter from the U.S. Food and Drug Administration ("FDA") to Jimmy John's Franchise, LLC ("Jimmy John's"), the franchisor of Jimmy John's sandwich shops, reminded the restaurant industry — and franchisors — of the importance of understanding and meeting the FDA's expectations for food safety. This is a good time to revisit best practices to achieve and maintain food safety throughout a large restaurant chain.

The warning letter detailed at least five foodborne illness outbreaks impacting 17 states over seven years that the Centers for Disease Control and Prevention ("CDC") and the FDA allege are tied to sprouts or cucumbers served at Jimmy John's franchised restaurants.<sup>1</sup>

Following tracing produce likely behind outbreaks of *Salmonella* in 2018 and *E. Coli* in late 2019, the FDA issued the warning letter to Jimmy John's. The FDA alleges that Jimmy John's failed to demonstrate that it has implemented long-term, sustainable corrections to its supply chain to assure the future safety of ingredients used in its products.<sup>2</sup> The FDA also issued a corresponding warning letter to Sprouts Unlimited Wholesale Foods, the produce supplier responsible for providing sprouts to Jimmy John's that sickened 22 people in November and December 2019.<sup>3</sup>

The FDA told the restaurant chain:

- "The presence of these pathogens in your food, as evidenced by links to foodborne outbreaks, causes your products to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) . . . in that they bear or contain an added poisonous or deleterious substance which may render them injurious to health."
- "[I]ntroduc[ing] or deliver[ing] for introduction into interstate commerce . . . food that is adulterated is a prohibited act under section 301(a) of the Act. . . ."
- "Further, receipt in interstate commerce of adulterated food is a prohibited act under section 301(c) of the Act. . . ."
- "[Y]ou have not provided FDA with any information demonstrating long-term, sustainable corrections have been implemented throughout your organization to prevent this violation from recurring in the future. For example, providing FDA with documentation of policies and practices demonstrating that you have made a corporate commitment to ensure produce . . . , specifically sprouts . . . sourced by any Jimmy John's restaurant will be procured from a farm or firm operating in compliance with the Produce Safety Rule, the Act, and, as applicable, the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods (PC Rule), 21 CFR Part 117."<sup>4</sup>

Food safety problems often arise through a franchise system's supply chain, whether at the growing, transport, processing, or handling stages. There are many reasons that food safety concerns arise, but, similar to this situation, many are tied to a potential lack of sufficient verification of national suppliers. Further, certain foods, like sprouts and some other types of fresh produce, are generally understood to present increased risks of microbial contamination and utilizing these ingredients may require more work to reduce risk.

The warning letter to a large, franchised restaurant chain is an important reminder for restaurant chains, franchised or not, to:

- Choose suppliers carefully and build enough supplier relationships and contractual flexibility to suspend purchases or stop purchases from a supplier that needs to improve food safety practices or that the FDA alleges is not compliant with FDA's food safety laws;
- Obtain signed pure food guarantees from each supplier requiring the supplier to warrant and guarantee, in writing, that its operations and products are in full compliance with all applicable food safety laws, including the Food, Drug and Cosmetic Act (the "Act"), in order to provide the restaurant chain with a defense to alleged violations of section 331(c) of the Act tied to the receipt of adulterated food by allocating responsibility to the supplier;<sup>5</sup>
- Conduct a food safety gap assessment to determine whether the restaurant chain's food safety system is robust enough to address identifiable hazards;
- Review and update food safety policies to address known or potential gaps and to achieve best practices;
- Utilize documented supplier verification procedures to evaluate and approve potential suppliers by reviewing the systems they have in place to control food safety hazards and whether their operations and production methods comply with all applicable food safety laws – there is also no substitution for annual food safety audits or inspections of key suppliers; and
- Educate franchisees – or individual restaurants - about food safety practices.

Although not a legal requirement for all food categories, restaurant chains should consider implementing hazard analysis critical control point (HACCP)-like principles in each restaurant, or, even better, at each point along the supply chain to ensure food safety by analyzing and controlling biological, chemical and physical hazards associated with certain food products. The recent warning letters do not cover new concepts, but serve as a reminder to restaurant chains, and franchisors of restaurant concepts, of the unfavorable spotlight that food safety failures can place on a brand and how such issues may strain franchisor/franchisee relationships.

---

<sup>1</sup> See [FDA Warning Letter to Jimmy John's Franchise, LLC](#), dated February 21, 2020.

<sup>2</sup> See *id.*

<sup>3</sup> See [FDA Warning Letter to Sprouts Unlimited Inc](#), dated February 21, 2020.

<sup>4</sup> See [FDA Warning Letter to Jimmy John's Franchise, LLC](#), dated February 21, 2020.

<sup>5</sup> As FDA clarified in its warning letter to Jimmy John's, "receipt in interstate commerce of adulterated food is a prohibited act under section 301(c) of the Act. . . ." See *id.*