

WARNING LETTER

Jimmy John's Franchise, LLC MARCS-CMS 599962 — FEBRUARY 21, 2020

Delivery Method:

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Product:

Food & Beverages

Recipient:

James North

President

Jimmy John's Franchise, LLC

2212 Fox Drive Champaign, IL 61820 United States

Issuing Office:

Division of Human and Animal Food Operations East VI

United States

WARNING LETTER

FY2020-HAFE6-01

Dear Mr. North:

The U.S. Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC), and state and local partners, have collaboratively investigated several outbreaks linked to Jimmy John's restaurants. In this letter we detail evidence from five outbreaks, including the most recent outbreak in the state of Iowa during December 2019 of human infections with *Escherichia coli* O103. The evidence demonstrates that your corporation, through your franchised Jimmy John's restaurants, engaged in a pattern of receiving and offering for sale adulterated fresh produce, specifically clover sprouts and cucumbers.

The pathogens associated with these outbreaks are Shiga toxin producing *Escherichia coli* (STECs) and *Salmonella enterica*. STECs can cause serious illness in humans, including diarrhea, often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called hemolytic uremic syndrome (HUS). HUS is most likely to occur in young children and the elderly. This condition can lead to serious kidney damage and death. *Salmonella* is a pathogenic bacterium that can cause serious, sometimes fatal, infections. These infections can be especially serious in young children, the elderly, and others with weakened immune systems. Healthy individuals may suffer short-term symptoms such as severe diarrhea, bloody diarrhea, fever, chills, abdominal discomfort, and vomiting. 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)[21 U.S.C. § 342(a)(1)] in that they bear or contain an added poisonous or deleterious substance which may render them injurious to health. The introduction or delivery for introduction into interstate commerce of food that is adulterated is a prohibited act under section 301(a) of the Act [21 U.S.C. 331(a)]. Further, receipt in interstate commerce of adulterated food is a prohibited act under section 301(c) of the Act [21 U.S.C. § 331(c)]. You can find the Act and its implementing regulations through links on FDA's home page at <https://www.fda.gov>.

Human Illness Outbreaks

1. November to December 2019; outbreak of human infections with *E. coli* O103 (STEC)

Iowa Department of Public Health reported that as of January 7, 2020, a total of 22 people from Iowa were infected with the outbreak strain of *E. coli* O103. Twenty of the 22 case individuals were interviewed by the Iowa Department of Public Health. Of the case individuals interviewed, 100 % reported eating at one or more of 15 Jimmy John's restaurants. Of the 20 interviewed, 45% (9) reporting eating sprouts in the week before their illness. Iowa Department of Public Health states this proportion is significantly higher than results from a survey of healthy people in which 3.3% reported eating sprouts in the seven days before being interviewed.

Iowa Department of Inspections and Appeals ascertained that (b)(4) of the 15 Jimmy John's restaurants received clover sprouts from (b)(4) clover sprouts during the period of interest. As further confirmation that sprouts served at your restaurants were the outbreak vehicle, samples of sprouts and sprout irrigation water collected by the firm that supplied the (b)(4) Jimmy John's restaurants yielded a strain of *E. coli* O103 that was highly related to the outbreak strain by whole genome sequencing, a state-of-the-art genetic subtyping method. The analytical work was done by (b)(4).

2. Outbreak of human infections with *Salmonella* Montevideo

The CDC reported that as of February 28, 2018, ten people were infected with the outbreak strains of *Salmonella* Montevideo in Illinois (2), Minnesota (2), and Wisconsin (6). Eight (80%) of these ten people ate meals at Jimmy John's restaurants in Illinois and Wisconsin the week before becoming sick. All eight people reported eating raw sprouts on sandwiches from Jimmy John's in Illinois and Wisconsin. One ill person in this outbreak reported eating raw sprouts purchased from a grocery store in Minnesota. All the *Salmonella* Montevideo isolates were closely related by whole genome sequencing.

The evidence supports that **(b)(4)** sprouts for the implicated Jimmy John's restaurants. **(b)(4)** shown in invoices collected by State and local partners, including the Illinois Department of Public Health, Minnesota Department of Health, the Minnesota Department of Agriculture, the Wisconsin Department of Agriculture, Trade and Consumer Protection, and the Wisconsin Department of Health Services, from various Jimmy John's locations the Minnesota grocery store and/or distributors.

3. Outbreak of human infections with *E. coli* O102 (STEC)

The CDC reported that as of August 1, 2014, 19 people were infected with the outbreak strain of *E. coli* O121 in Idaho, Montana, Michigan, Utah, California, and Washington. In interviews, 13 (81%) of 16 ill persons reported eating raw clover sprouts in the week before becoming ill. This proportion is significantly higher than results from a survey of healthy persons in which no more than 8% reported eating raw clover sprouts in the week before they were interviewed.

FDA's traceback investigation for 11 of the 19 case individuals identified seven points of service [POS] as the likely or most likely locations of their sprout exposures. Five (5) of seven (7) POS were identified as Jimmy John's restaurants. Clover sprouts served at each POC were sourced from the same sprout grower.

4. Outbreak of human infections with *E. coli* O157:H7 (STEC)

CDC reported that as of the end of October 2013, eight people from Colorado were infected with the outbreak strain of *E. coli* O157:H7. Of the eight persons interviewed by Colorado Department of Public Health and Environment, 100% report eating a sandwich with raw cucumbers at one of three Jimmy John's restaurants in the Denver metro area. No other ingredient exposure was as significant as cucumbers. FDA's traceback investigation identified that all three Jimmy John's restaurants involved in the outbreak received cucumbers from the same source during the period of interest.

5. Outbreak of human infections with *E. coli* O26

CDC reported that as of April 5, 2012, a total of 29 people from eleven states were infected with an outbreak strain of *E. coli* O26. Of the 27 persons interviewed, 85% (23) report eating sprouts at one of six Jimmy John's restaurant in the seven days preceding their illness. Though traceback investigation, FDA identified a single lot of seed grown and distributed by multiple sprouting firms including **(b)(4)** sprout operations that supplied the six Jimmy John's restaurants implicated in the outbreak.

Taken together, these outbreaks, which spanned over the past seven years and impacted no fewer than seventeen states demonstrate the corporate-wide supplier control mechanisms you have in place for receiving fresh produce are inadequate.

We acknowledge your parent company's, Inspire Brands, decision in December 2019 to destroy sprouts on hand in all of your Iowa Jimmy John's restaurants, and to implement an additional, one-time cleaning and sanitation at Iowa based Jimmy John's restaurants; however, neither you nor your parent company proposed any corrective actions to prevent these, or other Jimmy

John's restaurants, from receiving adulterated produce, specifically sprouts. According to your website, www.ownajimmyjohns.com[External Link Disclaimer](#), you have franchised approximately 2,800 Jimmy John's restaurants in 43 states. In your response to this letter, please describe and document steps you have or will take to prevent the receipt and sale of adulterated food at each of the approximately 2,800 Jimmy John's restaurants.

In May 2012, a meeting was held with FDA at your request. During that meeting, you expressed that you would offer only clover sprouts, and to only source clover sprouts from **(b)(4)** suppliers. Since that corrective action, your firm has been implicated in three additional sprout-related outbreaks. Documents from traceback investigations conducted by FDA, states and local partners demonstrate that in addition to **(b)(4)** sprouts, Jimmy John's restaurants are using multiple other sources of sprouts.

Although you stated that corrective actions were implemented following the 2019 and 2012 outbreaks, you 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 covered by the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule), Title 21 Code of Federal Regulations, Part 112 (21 CFR Part 112), specifically sprouts, and 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.

The above violations are not intended to be an all-inclusive list of violations that exist in connection with the food you receive and offer for sale at your restaurants. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure your firm complies with all requirements of federal law and implementing regulations. You should take prompt action to correct all violations noted in this letter. Failure to promptly correct these violations may result in enforcement action by FDA without further notice, including seizure and/or injunction.

Next Steps

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include the specific things you are doing to address this violation. You should include in your response documentation and information that would assist us in evaluating your corrections. If you believe you have complied with the Act, include your reasoning and any supportive information for our consideration. If you cannot complete all corrections within 15 days, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to Food and Drug Administration, Attention: Lauren Crivellone Compliance Officer, Office of Human and Animal Foods Operations, Division East Six, Compliance Branch, 550 West Jackson Boulevard, Suite 1500, Chicago, Illinois 60661. If you have any questions regarding this letter, you may contact Compliance Officer Crivellone via

email at Lauren.Crivellone@fda.hhs.gov. Please reference CMS # 599962 on any documents or records you provide to us and/or within the subject line of any email correspondence you send to us.

Sincerely,

/S/

William R. Weissinger, Program Division Director
Office of Human and Animal Foods
Division East 6

cc:

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