

April 5, 2021

Mr. William Marler, Esq.
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RE: Case Reviews, *E. coli* O103 Outbreak

Dear Mr. Marler:

I have reviewed documents related to the 2020 Jimmy John's Franchise, LLC linked outbreak including depositions, illness questionnaires, medical records and publicly available records. My assessment, and expert opinion, is based on my review of these documents, the history of sprouted seed related outbreaks, food safety research literature, popular press related to previous Jimmy John's Franchise, LLC outbreaks, and regulatory documents from the U.S. Food and Drug Administration (FDA).

In my professional opinion, Jimmy John's Franchise, LLC's decision to repeatedly ignore the ever-growing mountain of evidence related to the risks associated with selling raw sprouted seeds, and to not provide the resources necessary to food handlers to control cross-contamination when preparing foods in the same restaurant as where sprouts are handled, coupled with its failure to practice good risk communication towards customers about the hazards associated with consuming raw sprouted seeds, demonstrates a poor food safety culture.

The concept of food safety culture has been pointed to as the root of what keeps the global food supply safe from contamination and has been embraced by the FDA as part of their modernization of food regulation and the Global Food Safety Initiative.

A culture of food safety is built on a set of shared values that operators and their staff follow to produce and provide food in the safest manner. Maintaining a good food safety culture means that operators and staff know the risks associated with the products or meals they produce, know why managing the risks is important, and effectively manage those risks in a demonstrable way. In an organization with a good food safety culture, individuals are expected to enact practices that represent the shared value system, point out where others may fail, and learn from others' mistakes. In short, a positive food safety culture means food safety is important within the organization and is supported from the top down, empowering employees to protect customers above all else.

In my professional opinion, the best food producers, processors, retailers and restaurants, many of whom participate in the Global Food Safety Initiative, go above and beyond minimal government and auditor standards and implement strong food safety programs. There are several examples of businesses that do this, many of whom have been awarded the International Association of Food Protection's Black Pearl award

(IAFP, 2020), which is presented in recognition of a company's outstanding achievement in corporate excellence in food safety and quality. The best organizations use their own staff to demand ingredients from the best suppliers; use a mixture of encouragement and enforcement to foster safe practices in food purchasing, distribution and training; and communicate how risks are being reduced directly to consumers.

Frequent information sharing and regular communication about foodborne risks amongst executives, middle management, and frontline food handlers is also important to support a culture of food safety (Yiannas, 2009). Many food safety experts have advocated for an executive level position to access food safety risks, compose and communicate a food safety mission statement, establish a food safety budget, and manage the food safety responsibilities of employees.

Sprouts present a unique food safety challenge compared to other fresh produce. The sprouting process of high humidity and high temperatures provides optimal conditions for the growth and proliferation of pathogenic bacteria if introduced on the seed or at any other time in the sprouting process.

The food safety community has been aware of the risks associated with sprouted seeds for at least three decades.

Sprouted seeds have been known to be heavily colonized by bacterial biofilms during the sprouting process and are well recognized for their ability to support microbiological loads (Fett, 2000). Despite this bacterial community, sprouts retain acceptable sensory characteristics that appeal to consumers and, as such, cannot be effectively evaluated using spoilage sensory tests (odor, physical appearance, taste).

Sprout risk reduction during sprout production began appearing in scientific journals in 1995 (Ponka et al, 1995; Health Canada, 1996; Jaquette et al, 1996; Puohiniemi et al, 1997). Research published in a prominent food safety journal in 1996 stated that the sprouting environment, which facilitated the growth of Salmonella, was a serious public health concern requiring urgent attention based on the recent association of sprouts with foodborne illness. The researchers stressed that the results were not a recommendation for people to avoid sprouts at salad bars, but rather should serve as a wake-up call for those who produced and prepared the product.

Over twenty years ago, in 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) produced a report on microbiological safety evaluations and recommendations for sprouted seeds in which the authors concluded that contaminated seed, and thus sprouters, was the likely source for most reported sprout-associated outbreaks (NACMCF, 1999).

The first consumer warning about sprouts was issued by the U.S. Centers for Disease Control (CDC) in 1997. By July 9, 1999, FDA had advised all Americans to be aware of the risks associated with eating raw sprouts and that the best way to control the risk was to simply not eat raw sprouts.

In response to NACMCF recommendations, the FDA developed guidelines for the sprout industry in October 1999. This guidance identified a number of areas, from the farm to the sprouting facility, where the FDA believed immediate steps should be taken to reduce the risk of sprout-associated foodborne illness (FDA, 1999). These included recommendations that seeds should be subjected to one or more approved treatments for reducing pathogens on seeds and sprouts; and that treatment should be supplemented with microbiological testing of the spent irrigation water from each production lot to minimize the potential for distribution of a contaminated batch.

Since the late 1990s, the sprout production industry, regulatory agencies, and the academic community have been collaborating to improve the microbiological safety of raw sprouts, including the implementation of Good Manufacturing Practices (GMP), by establishing guidelines for safe sprout production and chemical disinfection of seed prior to sprouting. However, guidelines and best practices are only as good as their implementation. The consumption of raw sprouts is considered high-risk. As a result, sprouted seeds have been called out by the U.S. Centers for Disease Control and Prevention (CDC) as a food to avoid especially for young, elderly and immunocompromised persons, and are treated differently from other regulated fresh produce items by FDA. This can be seen in both the Food Safety Modernization Act (FSMA) in 2011, as well as in the U.S. Model Food Code going back prior to 2001, in which sprouted seeds were considered to be potentially hazardous foods and were not permitted to be served to highly susceptible populations.

More recently, there has been numerous presentations, scientific posters, and symposia at the International Association for Food Protection's annual meetings, the preeminent gathering of the food safety community. These include the 2012 symposium entitled, "Sprout Safety: What We've Done, What We've Learned and How We Can Continue to Move Forward," and 2014's "Microgreens and Sprouts under Microscope: Similarities and Differences in Botanic Structure, Agricultural Practices, and Food Safety Risks." In addition, a review of the past 10 years of meeting abstracts reveals that there have been over 50 posters and 80 presentations on sprout safety. Sprouted seeds food safety is amongst the most important and long-standing topics in the food safety world.

In 2012 FDA and the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) formed the Sprouts Safety Alliance (SSA) in an attempt to address some of these issues. The mission of this public-private alliance is to develop a core curriculum with training and outreach programs for stakeholders in the sprout production community in order to enhance the industry's understanding and implementation of best practices for promoting sprout safety, and of pending sprout safety regulatory requirements. The SSA has also provided guidance and inspection/audit checklists for buyers of sprouted seeds (SSA, 2011). In my professional opinion, anyone who is purchasing sprouts with a positive food safety culture should not only be aware of these resources, but should further be employing the SSA approach to supply chain verification.

Handling sprouted seeds in a restaurant setting can provide challenges, whether contaminated or not. This is evidenced by the FDA Model Food Code requirements to hold sprouted seeds under temperature control (designating them a Time/Temperature Control for Safety Food) and for restaurants who sprout their own seeds to apply for a variance to the code and implement a HACCP plan. This is not only because the sprouted seeds themselves provide a risk when consumed, but also because handling them leads to increased risks of cross-contamination that need to be controlled through the reduction measures. Essentially, having the increased likelihood that a pathogen enters on the sprouts, food employees/handlers need to be aware that there is a potential to move contamination from the sprouts to other foods, resulting in patrons who did not even consume the sprouts to become ill. This is not just a theoretical risk; it has been highlighted in multiple previous outbreak investigations. As an example, a historic case study in sprouted seed food safety demonstrates that cross-contamination happens. In a 1995 multinational outbreak of *Salmonella enterica* Serotype Newport infections due to contaminated alfalfa sprouts, public health experts wrote that they identified 133 cases in Oregon and British Columbia; 124 (93%) occurred in patients older than 18 years; 87 (65%) were female. Case patients were more likely than community control subjects to report having eaten alfalfa sprouts in the 5 days preceding illness (41% [17/41] vs 4% [3/75]; OR, 17.0; 95% confidence interval, 4.3-96.0). But in contrast to most foodborne outbreaks, only a minority of cases (in this outbreak, 41%) recalled eating the implicated food. This is likely because of cross-contamination of salad and sandwich bars or sprouts' concealed presence in other foods (Van Beneden et al, 1999).

Retailers, restaurants, and other food service operators who have served any potentially contaminated products need to be concerned about cross-contamination through hands (gloved or bare), food contact surfaces, and utensils through contact with the potentially contaminated products. Cross-contamination and handwashing have been identified through multiple independent studies, as well as the FDA's risk factor studies, as amongst the most problematic of food handlers' practices within a foodservice setting (FDA, 2018). In my professional opinion, cross-contamination within the restaurant also more likely than not led to illnesses with Plaintiffs Knorr and McDonald as they did not report eating sprouts directly but have whole genome matches with the outbreak strain.

In my tracking of foodborne pathogens associated with raw or fresh consumed (uncooked/heated) sprouted seeds, I have collected information on 79 outbreaks resulting in 11,498 confirmed illnesses since 1973 (see attachment A, Sprout-associated--outbreaks-4-5-21.xls). Numerous pathogens have either been implicated in sprout-associated outbreaks, including *Bacillus cereus*, *Listeria monocytogenes*, *Shigella spp.* and *Yersinia enterocolitica*. But the vast majority of illnesses (well over 90 %) have been due to *Salmonella enterica* serovars and Shiga toxin-producing *Escherichia coli*, both pathogens that have been identified as contributing to a high public health burden. The majority of these outbreaks have been linked to a contaminated seed source or sanitation in sprouting – both supplier issues that can be exacerbated by a poor food safety culture where standards are not set, and where buyers do not evaluate what practices are being implemented.

In 2011, a landmark outbreak of *E. coli* O104 linked to sprouted seeds led to 53 deaths and over 4,000 sick people (Altmann et al, 2011). This outbreak dominated the food safety popular press, trade magazines, online listservs, and food safety blogs. It would have been very difficult for any food safety professional not to see this coverage. As a result, since that time (if not before), when asked what foods they avoid based on their knowledge of contamination and history, food safety professionals often list raw sprouted seed at the top of the list. In a 2019 retrospective study of foodborne pathogens associated with fresh produce, derived from multistate foodborne outbreaks of bacterial infection in the U.S. from 2010 to 2017, the most frequently identified food vehicle within the vegetable category was sprouts (27.6% of all outbreaks) (Carstens et al. 2019). In 2021, the FDA also completed a risk-ranking model to support food safety intervention resources for foods in the U.S., and this model identified sprouts as tied for fourth on the list of risky foods (ahead of shellfish, fresh cut leafy greens and some cheeses) (FDA, 2021). The CDC still specifically lists sprouts as a risky food on their public communication related to avoiding food poisoning, accompanied by the statement “Some foods are more associated with foodborne illnesses and food poisoning than others. They can carry harmful germs that can make you very sick if the food is contaminated.” (CDC, 2020)

Jimmy John’s Franchise, LLC has a history of sprouted seed-linked outbreaks prior to the 2020 event (Sol Erdozain et al, 2013). After two previous outbreaks in 2008 and 2009, a third Jimmy John’s, LLC/sprout-linked outbreak occurred from November 2010 into 2011, leading to 140 illnesses (CDC, 2011; Illinois Department of Public Health, 2010). By the end of December 2010, a sprout supplier, Tiny Greens Farm, was implicated in the outbreak (FDA, 2010). Jimmy John’s owner, John Liautaud, responded by stating the sandwich chain would replace alfalfa sprouts with clover sprouts since they were allegedly easier to clean (Associated Press, 2011).

In FDA’s investigation of the Tiny Greens facility numerous failures were found which may have led to pathogen contamination. According to the FDA report, “the company grew sprouts in soil from the organic material decomposed outside without using any monitored kill step on it,” mold was found in the mung-bean sprouting room, and the antimicrobial treatment for seeds was not demonstrated to be equivalent to the recommended FDA treatment (Roos, 2011).

In late December 2011, less than one year after making the switch to clover sprouts, Jimmy John’s Franchise, LLC was linked to a fourth sprout related outbreak, *E.coli* O26 (CDC, 2012). In February 2012, sandwich franchise Jimmy John’s Franchise, LLC announced they were permanently removing raw clover sprouts from their menus (Liddle, 2012; Sol Erdozain et al, 2013). But sprouted seeds did return to menus, resulting in the 2020 outbreak.

Sprouted seeds have been removed from a variety of other businesses. For example, Erbert and Gerbert’s Sandwich Shops removed alfalfa sprouts from their menu, Walmart stores stopped selling raw sprouts nationwide in 2010, and Kroger followed suit in 2012. Other restaurants have chosen to not sell sprouted seeds in new menu items as a precaution (Denn, 2012; Huffington Post 2012).

In my professional opinion, the February 2020 warning letter from FDA to Jimmy John's about continuous use of sprouts is unique. In my professional experience reviewing warning letters and working with businesses to respond to regulatory actions, I have never seen a situation like this, where a firm said they would do something in an official meeting with FDA, and then eventually decided to do something else (FDA, 2020).

From that letter, "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 [redacted] 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 [redacted] sprouts, Jimmy John's restaurants are using multiple other sources of sprouts."

As a response to the multiple outbreaks, Jimmy John's Franchise, LLC has included various risk messages including in online orders, where a less than appetizing warning pops up: "The consumption of raw sprouts may result in an increased risk of foodborne illness and poses a health risk to everyone. Click 'Yes' if you understand the potential risks, or 'Cancel' if you'd like to continue without adding sprouts."

In stores, one response was to include a poster of a skull and cross bone picture and the following text:

"THE CONSUMPTION OF RAW SPROUTS MAY RESULT IN AN INCREASED RISK OF FOODBORNE ILLNESS AND POSES A HEALTH RISK TO EVERYONE. EXPECTANT MOTHERS, DAREDEVILS, CUTE OLD LADIES, INFANTS, VEGANS & VEGETARIANS, GRUMPY OLD MEN, INVINCIBLE TEENAGERS, YOUR AVERAGE JOE, PERSONS

WITH WEAKENED IMMUNE SYSTEMS AND EVEN THE STRONGEST SUPERHEROES, PLEASE BEWARE. IF YOU DON'T BELIEVE ME, CONTACT YOUR PHYSICIAN OR LOCAL PUBLIC HEALTH DEPARTMENT! CHILDREN UNDER 18 MUST GET THEIR PARENTS' PERMISSION."

In my professional opinion, keeping sprouted seeds on the menu and then taunting consumers with sassy posters showing a cartoon and campy text was a brazen move by Jimmy John's Franchise, LLC, and goes against good risk communication practices. Risk communication research has revealed that consumers need to understand the context of a risk to be able to identify and employ informed decision making. Familiarity also plays a strong role in consumer perception of a risk, as does trust. Behavior and risk communication are more likely to be impacted when targeting both knowledge and individual intention.

Making light of the numerous outbreaks and thousands of illnesses that have been linked to these products is not really in line with what Jimmy John's CEO James North said following one of the previous outbreaks: "Food safety and the welfare of our customers are our top priorities and not negotiable in our business." (Pantagraph Staff, 2018)

Passing the responsibility to consumers to conduct their own risk assessments, as Jimmy John's Franchise, LLC has consistently done over the last 15 years relies on solid validation that the practices (avoidance and controlling cross-contamination) will work and a keen focus on effective risk communication to allow for consumers to make an informed decision. In my professional opinion, and from viewing documents related to this case, previous cases and those that are publicly available, Jimmy John's Franchise, LLC does not appear to acknowledge the history or risks of consuming raw sprouted seeds, and has not learned from their past issues. The firm appears to have a poor food safety culture, has left risk reduction decisions in the hands of their patrons, and they have not armed them with the tools to do so.

A handwritten signature in blue ink, appearing to read 'Benjamin Chapman', with a long horizontal stroke extending to the right.

Benjamin Chapman, PhD

References

Altmann M., Wadl M., Altmann D., Benzler J., Eckmanns T., Krause G., Spode, A., & an der Heiden, M. 2011. Timeliness of surveillance during outbreak of Shiga toxin–producing *Escherichia coli*, Germany, 2011. *Emerging Infectious Diseases*, 17. doi: 10.3201/eid1710.111027

Associated Press. 2011. Jimmy John's changing to clover sprouts. *Chicago Sun-Times*. Accessed at: <http://southtownstar.suntimes.com/business/3255479-420/sprouts-alfalfa-john-clover-jimmy.html>.

Carstens, C. K., Salazar, J. K., & Darkoh, C. (2019). Multistate Outbreaks of Foodborne Illness in the United States Associated With Fresh Produce From 2010 to 2017. *Frontiers in microbiology*, 10, 2667. <https://doi.org/10.3389/fmicb.2019.02667>

CDC. 2011. Investigation update: multistate outbreak of human *Salmonella* i 4,[5],12:i- infections linked to alfalfa sprouts. Accessed at <http://www.cdc.gov/salmonella/i4512i-021011/index.html>.

CDC. 2020. Foods That Can Cause Food Poisoning. Accessed at: <https://www.cdc.gov/foodsafety/foods-linked-illness.html>

Denn, R. 2012. Looking for sprouts? You might have to look hard, and think twice. *The Seattle Times*. Accessed at http://seattletimes.nwsourc.com/html/allyoucaneat/2017496518_looking_for_sprouts_you_might.html.

FDA. 1999. Guidance for industry: Sampling and microbial testing of spent irrigation water during sprout production. Accessed at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm120246.htm>.

FDA. 2010. FDA: Don't eat certain lots of tiny greens brand alfalfa sprouts or spicy sprout. Accessed at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm238188.htm>

FDA. 2018. FDA Report On The Occurrence Of Foodborne Illness Risk Factors In Fast Food And Full-Service Restaurants, 2013-2014. Accessed at: <https://www.fda.gov/media/117509/download>

FDA. 2020. Warning Letter: Jimmy John's Franchise LLC. Accessed at: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jimmy-johns-franchise-llc-599962-02212020>

FDA. 2021. Risk-Ranking Model for Food Tracing. Accessed at: <https://www.cfsanappsexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracing/>

Fett, W. F. 2000. Naturally occurring biofilms on alfalfa and other types of sprouts. *Journal of Food Protection*, 63, 625-32.

Health Canada. 1996. Enterohemorrhagic E. coli infection Japan. *Canada Communicable Disease Report*, 22, 199-200.

Huffington Post. 2012. Kroger: Sprouts Are Too Unsafe To Be Sold. https://www.huffpost.com/entry/kroger-sprouts_n_2000828

IAFP. 2020. Black Pear Award. Accessed at: <https://www.foodprotection.org/about/past-awardees/black-pear-award/>.

Illinois Department of Public Health. 2010. Salmonella outbreak investigation. Accessed at: <http://www.idph.state.il.us/public/press10/12.17.10AlfalfaSproutss.htm>.

Jaquette, C.B., Beuchat, L.R. & Mahon, B.E. 1996. Efficacy of chlorine and heat treatment in killing *S. stanley* inoculated onto alfalfa seeds and growth and survival of the pathogen during sprouting and storage. *Applied Environmental Microbiology*, 62, 2212-2215.

Liddle, A. 2012. Jimmy John's pulls sprouts from menu. *Restaurant News*. Accessed at: <http://nrr.com/article/jimmy-johns-pulls-sprouts-menu>.

NACMCF. 1999. Microbiological safety evaluations and recommendations on sprouted seeds.

Pantagraph Staff. 2018. Accessed at: https://www.pantagraph.com/news/local/sprouts-suspected-in-salmonella-cluster/article_3033ee81-190b-586d-b424-0641206d7f7b.html

Ponka, A., Anderson, Y., Sitonen, A., deJong, B., Jahkola, M., Haikala, Kuhmonen, A., & Pakkala, P. 1995. Salmonella in alfalfa sprouts. *Lancet*, 345, 462-463. doi:10.1016/S0140-6736(95)90451-4.

Puohiniemi, R., Heiskanen, T., & Siitonen, A. 1997. Molecular epidemiology of two international sprout-borne Salmonella outbreaks. *Journal of Clinical Microbiology*, 35, 2487- 2491

Roos, R. 2011. FDA details hazards at Illinois sprout producer. *Center for Infectious Disease Research & Policy (CIDRAP) News*. Accessed at: <http://www.cidrap.umn.edu/cidrap/content/fs/food-disease/news/feb0711sprouts.html>.

Sol Erdozain, M., Allen, K. J., Morley, K. A., & Powell, D. A. 2013. Failures in sprouts-related risk communication. *Food Control*, 30(2), 649-656.

SSA, 2011. Auditing and Inspection Checklist for Sprouting Facilities. Accessed at https://www.ifsh.iit.edu/sites/ifsh/files/departments/ssa/pdfs/ifsh2011_sproutsafetyaudit.pdf.

Van Beneden C.A., Keene W.E., Strang R.A, et al. Multinational Outbreak of Salmonella enterica Serotype Newport Infections Due to Contaminated Alfalfa Sprouts. JAMA. 1999;281(2):158–162. doi:10.1001/jama.281.2.158

Yiannas, F. 2009. Food safety culture: Creating a behavior-based food safety management system. New York: Springer Science.