History of Produce Safety

Outbreaks and Policies that have Shaped Produce Safety and the Broader Food Industry
In the years leading up to 1906, Dr. Harvey Wiley, a chemist at the USDA conducted a series of experiments evaluating the effect of various food preservatives on human volunteers. This group became known as the “Poison Squad”, consuming foods laced with preservatives or additives such as formaldehyde, borax, or sawdust that were commonly found in food at the time. These experiments illustrated the need for oversight and control of the safety of the US food supply. Simultaneously, in 1904, Upton Sinclair, a young journalist, went undercover in Chicago’s meat packinghouses, experiencing first-hand horrific practices that were unsanitary and unsafe for both the workers and consumers of the products. His fictionalized account of Chicago’s meat packing industry was first released in a magazine in 1905 and subsequently in 1906 as a book (The Jungle). After catching the attention of President Roosevelt, the packinghouses were further investigated, and the Federal Meat Inspection Act was quickly passed. The passage of this act opened a door for the Pure Food and Drug Act, spearheaded by Dr. Wiley, whose work for years prior had shown the need for such regulations. Ultimately, the Pure Food and Drug Act prohibited the sale of misbranded or adulterated food and drugs. At its core the act promoted transparency from the industry to the consumer. Initially administered by the Bureau of Chemistry, the act also paved the way for the establishment of the FDA as we know it today. In 1907, a Board of Food and Drug Inspection was established to help create policy to enforce this new act with Dr. Wiley appointed as the first commissioner. In 1930 the Board of Food and Drug Inspection became The Food and Drug Administration.

This act replaced the 1906 Pure Food and Drug Act, and while it took years to develop, it gained significant momentum in 1937 after the horrific death of 107 people due to a widely used drug formulated with a highly toxic chemical. In addition to granting FDA the authority to regulate drugs, medical devices, and cosmetics, The Food, Drug, and Cosmetic Act established the definition of “adulterated” foods. It also established three standards for food that are still seen today: standard of identity, standard of quality, and a standard regulating the fill of the container. The first set of standards centered around the use of sodium benzoate as a preservative in tomato products, namely ketchup. Shortly after, standards were established for a host of other products including jams, juices, canned goods, and dairy products.
**1993**

**E. coli O157:H7 JACK IN THE BOX OUTBREAK**

Between 1992 and 1993, over 700 people across Washington, Idaho, California, and Nevada became infected with *E. coli* O157:H7, and 4 died after eating undercooked beef patties from a popular fast food chain.

Despite Washington State increasing the required internal temperature of beef patties from the national 140°F to 155°F (the required temperature required to kill *E. coli*), further investigation of the outbreak revealed that the beef patties did not consistently reach this temperature. *E. coli* O157:H7 is typically found in the gut of healthy animals, and source investigation determined that during slaughter, the surface of the meat became contaminated and ultimately mixed in with the final ground product.

The aftermath of this crisis became a convoluted blaming web with the Jack in the Box franchises suing the parent company, Jack in the Box blaming its suppliers, and the USDA along with state health officials blaming Jack in the Box for not cooking their hamburgers to 155°F as required by the state. Despite who is to blame, the major lesson learned from this tragic event is the importance of following science-based food safety rules and regulations. Washington state had raised its required temperature for ground beef from the national 140°F to 155°F in response to a few small *E. coli* outbreaks in meat products in previous years. The knowledge of how to control the risk was known, and it simply needed to be implemented. This case study also illustrates the impact a single outbreak event can have on the broader industry. As a result of the outbreak, consumer mistrust in the product negatively impacted the meat packaging industry for many years to come.

**Impact:**

- *E. coli* O157:H7 became a reportable illness in 33 new states (increased from just 12 states).
- In 1994, USDA-FSIS declares *E. coli* O157:H7 to be an adulterant and begins a microbiological testing program to detect *Escherichia coli* O157:H7 in raw ground beef.
- HACCP became required in meat-processing establishments.
- While not a direct response, this outbreak was a catalyst for the creation of the Food borne Diseases Active Surveillance Network (FoodNet), housed in the CDC, which works to track and report on food borne outbreaks and trends.

**1998**

**FDA RELEASES GAP GUIDELINES**

Just over 10 years prior to the ushering in of the Food Safety Modernization Act, much of the information included with this guidance is echoed within the Produce Safety Rule. While this guidance is not legally binding nor a regulatory requirement, it clearly established a precedent that was necessary to later implement into legal standards through the development of FSMA.
GFSI was established in 2000 by The Consumer Goods Forum to address food safety incidents that had become increasingly frequent. In addition, GFSI hoped to address ‘audit fatigue’ in which suppliers were required to prepare for multiple, nearly identical food safety audits for different customers. Through its maintenance of a benchmarking system, GFSI aims to support the development of gold-standard 3rd party food safety audits. Every 5 years, a new guidance document is released on “conforming food safety management standards”. This document is used to compare to and approve auditing bodies with the intention of increasing consistency in food safety practices. Today, GFSI recognized auditing schemes are widely accepted by major buyers of fresh produce.

While a wide variety of menu items at Sheetz were initially associated with the outbreak, the common factor between all implicated products was produce, namely lettuce and tomatoes. Epidemiological traceback initially linked 5 different serotypes of *Salmonella enterica* to the outbreak; however, later investigation found *Salmonella Anatum* in an unopened bag of tomatoes, and PFGE matched some of the strains from infected patients to those isolated from the tomatoes. FDA along with state health departments conducted further traceback investigations at the level of the distributor, packers, and growers. Environmental sampling of the packing houses and associated farms did not show a clear source of contamination at the tomato slicing facility.

Impact: The outbreak, along with many past unresolved outbreaks of *Salmonella* Newport ultimately triggered FDA to conduct a longitudinal study on the “Delmarva” peninsula, a major east coast tomato growing region. Using whole genome sequencing (WGS), extensive environmental sampling found consistent positives in streams, creeks, sediment, and geese droppings, indicating certain *Salmonella* strains as being endemic to the region. This knowledge allowed the implementation of effective controls.

In 2004, a *Salmonella* outbreak linked to fresh, sliced Roma tomatoes on deli sandwiches sold at Sheetz convenience stores on the East Coast caused 429 illnesses across 9 states.

2000 ESTABLISHMENT OF THE GLOBAL FOOD SAFETY INITIATIVE

The Global Food Safety Initiative (GFSI) is a private organization that maintains a benchmarking scheme for food safety management systems with the goal of creating a common set of requirements for food safety standards.

2004 SALMONELLA CONTAMINATED TOMATOES
2006

**E. COLI O157:H7 IN SPINACH**

In the summer of 2006, a large *E. coli* O157:H7 outbreak resulting in over 200 illnesses and 5 deaths across 26 states was traced back to contaminated fresh spinach.

**Impact:**

- The USDA's Economic Research Service reported a significant drop in spinach sales and, for a period, leafy greens as a whole following the outbreak.
- New awareness was brought to the safety of growing, harvesting, and processing of fresh produce, ultimately leading to the establishment of the California and Arizona Leafy Greens Marketing Agreement (LGMA).
- Finally, it demonstrated the power of FDA to shut down an industry in the event of an undefined or untraceable outbreak if it is thought to best protect public health.

On September 14th, the FDA issued a public warning against bagged spinach advising consumers not to eat the product. As the case counts grew, the FDA took drastic actions and on the 16th issued a revised warning against the entire commodity, asking the public to avoid any type of fresh spinach or spinach-containing product. Epidemiological traceback determined the source of the outbreak to be from a single farm in San Benito County, California. Upon further investigation of the farm and surrounding environment it was noted that the farm was near the San Benito River which cattle and pigs in the area had ready access to. PFGE found that *E. coli* positive samples of cattle feces and river water matched the outbreak strain. While the farm used well water, not river water, later studies suggested that when ground water levels fall below that of the riverbed, the river water can flow into the groundwater source. Water level and rainfall reports later analyzed provided evidence that this phenomenon was suspected to have occurred in the summer of 2006.

### Impact:

*Salmonella* Saintpaul caused 1,300 illnesses (with additional cases in Canada) over 3 months with 252 hospitalizations across 43 states and 2 deaths. While initially linked to raw tomatoes, extensive epidemiological and microbiological testing provided significant evidence against tomatoes as a likely source and revealed that jalapeño and serrano peppers grown in Mexico were in fact the original source of contamination.

On June 7th the FDA issued a nationwide warning against 3 types of tomatoes thought to be implicated in the outbreak. The MN Department of Health determined that it was not tomatoes but rather peppers after illnesses continued to come in weeks after tomatoes were no longer sold in stores and restaurants. They alerted FDA of this trend, suggesting peppers were the real source after conducting a traceback investigation that led them to distributors in California and Texas who purchased product from farms in Mexico. Finally, on July 17th the tomato warning was lifted after the mounting evidence was obtained. Soon after, on July 21st the FDA isolated the outbreak strain from jalapeño peppers as well as from an irrigation water sample on one of the farms suspected to be a part of the outbreak. In an epidemiological case study conducted following this outbreak, it was noted that cases were significantly associated with eating raw tomatoes, eating at a Mexican-style restaurant, and eating salsa or having raw jalapeño peppers in the household. Items more often used as ingredients in various products- such as peppers- create even more problems as consumers may not be aware of everything they are consuming.

### Impact:

Fresh produce is seldom consumed in a vacuum, and more frequently is consumed as an ingredient or in combination with other fresh products. This can pose a challenge in identifying which item the outbreak originated from, and it highlights the necessity of each leg in the outbreak investigation process: epidemiology, traceback, and food and environmental testing data.

Unfortunately, public health decisions must often be made when outbreak data is ambiguous or incomplete. This event illustrates the delicate balancing act that the FDA faces between promoting public health and preventing unnecessary negative impacts on companies and commodity industries as a whole through the issuance of broad public advisories.
Throughout 2008 and 2009, 714 people became infected with *Salmonella* Typhimurium across 46 states following the consumption of contaminated peanut butter or peanut butter containing products. Peanut Corporation of America (PCA) fabricated pathogen testing certificates of analysis and knowingly released contaminated product into commerce.

In 2009, epidemiological tracebacks and investigations conducted by state health departments isolated *Salmonella* from both opened and unopened 5-pound containers of King Nut brand peanut butter produced by PCA. In a report released by the FDA, multiple instances were cited where product was released into commerce despite PCA’s own internal product tests that resulted in *Salmonella* positives. An FDA inspection of the facility and processing operation revealed that the facility did not clean the production line after *Salmonella* Typhimurium was originally found in the paste in September 2008. While roasting was established as a critical control point and recognized as the kill-step, it was not validated to effectively eliminate the pathogen of concern (*Salmonella*). Traceback and recalls spanned the course of two years due to the nature of the product and its use in many other foods, and negligence by the company in dealing with the contamination made traceback difficult. PCA supplied its products to hundreds of small, family owned and multibillion-dollar companies who used the peanut products as an ingredient in their foods.

**Impact**

- This outbreak demonstrated the serious consequences faced by food safety leaders and company executives who falsify records and knowingly ship adulterated food.
- Former individuals in PCA top leadership were charged with mail and wire fraud, introduction of adulterated and misbranded food into interstate commerce, conspiracy and obstruction of justice.
- In 2014, former owner, Stewart Parnell, and food broker, Michael Parnell, were sentenced to 28 and 20 years in prison. Mary Wilkerson, former quality assurance manager, was sentenced to 5 years.
In 2011, whole cantaloupes from Colorado contaminated with *L. monocytogenes* caused 147 cases of listeriosis across 28 states, and led to 33 deaths.

Environmental and product sampling yielded positives for *L. monocytogenes* and PFGE illustrated that these were a match to the outbreak strain collected from patients. **FDA investigations pointed to two probable opportunities for cross-contamination: the use of wash water without antimicrobial treatment, and the use of processing equipment formerly used for rarely consumed raw produce without adequate sanitation between use.** Reports of an audit conducted in the weeks leading up to the outbreak noted that wash water was a potential problem due to the use of recirculated water without any antimicrobial treatment to eliminate potential pathogen cross-contamination. Further, FDA investigation and evaluation of the growing and processing environments noted equipment that was difficult to appropriately clean and sanitize, as well as improper draining on the processing floor which led to standing pools of water. The lack of a pre-cooling step prior to cold storage was later understood as a compounding factor, creating an ideal environmental for the proliferation of *Listeria*.

**Impact:** Until the 2011 outbreak, *Listeria* was not recognized as a high risk within the cantaloupe industry. The outbreak additionally highlighted the importance of using appropriate antimicrobial cross-contamination prevention measures and of using packing equipment suitable for the produce being packed, particularly if purchasing the equipment used.

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**2011 FSMA: PRODUCE SAFETY RULE**

In 2011 the Food Safety Modernization Act (FSMA) was signed into law, the first major change to food safety policy in the US since the 1938’s Food Drug and Cosmetic Act over 70 years prior. The act ushered in a new wave of food safety policy that employs preventative rather than reactive measures to ensuring the safety of the food supply chain.

The Produce Safety Rule is the first regulation to establish minimum safety standards for the growing, harvesting, packing, and storing of produce and was published in its final form in 2015. Exemptions to the rule include produce that is rarely consumed raw (a list of these products can be found on the FDA’s website) as well as farms with annual sales averaging < $25,000 over the past three years. The rule is made up of several parts including agricultural water; biological soil amendments; domesticated and wild animals; worker training, health, and hygiene; equipment, tools, and buildings; and the production of sprouts.

The FDA created 7 major rules to assist in FSMA’s implementation.
In 2015, contaminated caramel apples led to a multistate listeriosis outbreak resulting in 35 illnesses and 7 deaths.

On January 6th an apple packing facility in central California initiated a recall of Granny Smith and Gala apples after environmental testing showed contamination with *Listeria monocytogenes*. Three different processors using these apples in their caramel apple products also initiated a recall after being notified that their product could be contaminated. Illness onset ranged from October 17th, 2014 to February 12th, 2015. Following the product recall, FDA labs employed PFGE as well as WGS technology and found that the strain from the clinical cases matched those found in product and environmental samples. FDA investigation of the processing operation revealed *L. monocytogenes* on polishing brushes, drying brushes and inside wooden bins on a packing line. Further research into how *Listeria* survived on the skin of the apples revealed that the skin, along with the bacteria, was pushed into the flesh when the sticks were inserted as part of caramel apple production. The caramel coating also may have contributed to the issue by creating a microenvironment between the skin and caramel, which proved to be ideal for the growth of *Listeria*. While localized to a single California producer and three downstream processors, the impact of the outbreak affected the wider apple industry, taking a toll on marketing and sales.

**Impact:** This was the first major outbreak involving apples - prior to this they were considered a relatively safe product since the surface of a whole apple generally lacks the nutrients and water activity optimal for growth. Similar to the 2011 outbreak in cantaloupe, historical lack of a recall or outbreak in a product or commodity does not confer product safety, but rather suggests the need for a critical evaluation of where the risk could lie and what that risk might be for the product.

This outbreak also highlighted the importance for the produce industry to consider what the end use of their product will be, whether that be by another manufacturer or at the consumer level.
In the summer of 2018, two outbreaks of *Cyclospora cayetanensis* were detected in fresh produce. Beginning in June, FDA reported an outbreak linked to vegetable trays containing broccoli, cauliflower, carrots, and dill dip. A total of 250 cases were confirmed associated with this outbreak. In July, another outbreak was reported across the Midwest. Epidemiological traceback and FDA analysis confirmed that salad mix used by a large fast food chain, supplied by a fresh-cut processor, was a major source of this outbreak. A total of 511 confirmed cases of *Cyclospora* infections were associated with consumption of the salad mix. Further traceback investigation by the FDA was unable to pinpoint the original source of contamination for either outbreak.

**Impact:** Until 2018, *Cyclospora* had been considered a risk primarily on fresh produce imported from tropical countries. These outbreaks were the first major indication that *Cyclospora* may be present in the US, either endemic within the population or within the growing environment. An industry-led Blue Ribbon Panel was formed to address these challenges and to identify research needs, as much is still unknown about *Cyclospora* presence within the US or how producers can prevent or treat the parasite within the production chain.

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**2018 ROMAINE LETTUCE E. COLI O157:H7 OUTBREAKS**

In April 2018, an outbreak linked to romaine lettuce resulted in 210 cases of *E. coli* O157:H7 with 96 hospitalizations and 5 deaths.

Epidemiological and traceback evidence indicated the Yuma, AZ growing region as the likely source of the outbreak. FDA also used whole genome sequencing to link the clinical strain to *E. coli* found in water samples taken from an irrigation canal in the Yuma growing region. A large concentrated animal feeding operation (CAFO) was located directly adjacent and uphill from the same irrigation canal, leading many to suspect the CAFO as the ‘smoking gun’ for contamination. However, the exact route of transmission was ultimately undetermined.

**Impact:** Given the size and scope of the outbreak, an industry-led Leafy Greens Task Force was formed to address the identified risk factors associated with the outbreak. As a result of the task force, certain requirements within the Leafy Greens Marketing Agreement (LGMA) food safety guidelines in California and Arizona were revised, including an increased minimum distance for a field to be located away from nearby CAFOs.

This outbreak similarly highlighted traceability challenges within leafy greens, as well as the inability for foodservice and individual consumers to identify the regional source of their romaine lettuce. While the FDA outbreak advisory informed consumers to discard romaine specifically from the Yuma, AZ growing region, many were required to discard all their romaine due to unknown source region.
In the Fall of 2018, another romaine lettuce outbreak occurred, this time originating from California as the growing season transitioned from California to Arizona.

Although much smaller (62 total illnesses, 25 hospitalizations) than the previous spring romaine outbreak from Yuma, this outbreak gained widespread attention in part due to the announcement occurring immediately before the Thanksgiving holiday, but also due to the widespread scope of the FDA advisory. Again due to traceability challenges, a particular brand or region was unable to be identified. On November 20, FDA issued a food safety advisory recommending all consumers discard romaine lettuce, regardless of source. On November 26, FDA announced a narrower scope, identifying six CA counties as the likely source of contaminated produce. Following many conversations with government, association, and industry representatives, romaine product was ultimately allowed back on store shelves following a voluntary agreement for industry to label packages with their provenance, or, regional source. During the FDA’s on-site investigation, samples from sediment within a reservoir on a Santa Barbara county farm was found to contain the outbreak strain. This reservoir water was suggested to be a source of contamination as it was used extensively as agricultural water across the farm; however, traceback indicates that this farm did not supply all of the contaminated product. The specifics of the contamination event are unknown. Potential contact could have been made by direct application to the crop or use of the water on harvesting equipment food contact surfaces.

**Impact:**

Although not related to the Yuma outbreak strain, WGS did find clinical matches of the fall 2018 outbreak strain to previously unidentified outbreaks in the fall of 2017 and 2016, indicating some manner of seasonality linked to the contamination source.

Similar to the spring outbreak response, an even broader industry Romaine Task Force co-led by United Fresh Produce Association and Produce Marketing Association was developed to further address identified challenges associated with the romaine outbreaks. The task force was made of a broad group of industry leaders, academics, and government and public health representatives and was split into four focus areas: science-based prevention, traceability, provenance labeling, and outbreak investigation improvements. The final report for the task force was published in September 2019.

In the fall and winter of 2019 we once again see issues arise with the contamination of *E. coli* O157:H7 on romaine lettuce grown in the Salinas Valley of California. WGS revealed that three unique strains resulted in three separate outbreaks (167, 11, 10 illnesses respectively) occurring over November and December of that year.

**Impact:** The frequency of these outbreaks not only highlights the ongoing importance of food safety preventative measures for romaine lettuce, but also that there remain many ‘unknowns’ with regard to specific contamination routes and seasonality. Organizations that fund produce safety research, such as the Center for Produce Safety (CPS) remain as important as ever. In response to the events of this outbreak, the LGMA modified its stance on the treatment of irrigation water in order to mitigate the risk that contaminated well or surface water poses.
**Pure Food and Drug Act**


**Food Drug and Cosmetic Act**


**1993 Jack in the box E. coli outbreak**

https://www.cdc.gov/mmwr/preview/mmwrhtml/00020219.htm


**1998 GAP Guidelines**


**2000 Global Food Safety Initiative**

https://mygfsi.com/who-we-are/overview/

**2004 Salmonella outbreak in Tomatoes**

https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5413a1.htm

**2006 E. coli outbreak in Fresh Spinach**


**2008 Salmonella associated with Tomatoes**


https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5734a1.htm

https://vegetablegrowersnews.com/article/cleaning-up-the-salmonella-mess-will-take-a-long-time/


**2008-09 PCA Salmonella Scandal**


**2011 Listeria outbreak in Cantalopes**


**2011 Food Safety Modernization Act**


**2015 Listeria monocytogenes in caramel apples**

https://www.cdc.gov/mmwr/volumes/68/wr/mm6803a5.htm

2018 *Cyclospora* Outbreak

https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-multistate-outbreak-cyclospora-illnesses-linked-fresh-express-salad-mix-served

https://www.aappublications.org/news/2019/01/09/mmwr010919

https://www.cdc.gov/mmwr/volumes/67/wr/mm6739a6.htm?s_cid=mm6739a6_w

2019 Romaine lettuce outbreaks


2018 Romaine Lettuce outbreaks

https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-summary-factors-potentially-contributing-contamination-romaine-lettuce-implicated-fall

Document created by Rebecca Bland, M.S. candidate at Oregon State University and 2020 United Fresh Food Safety intern.