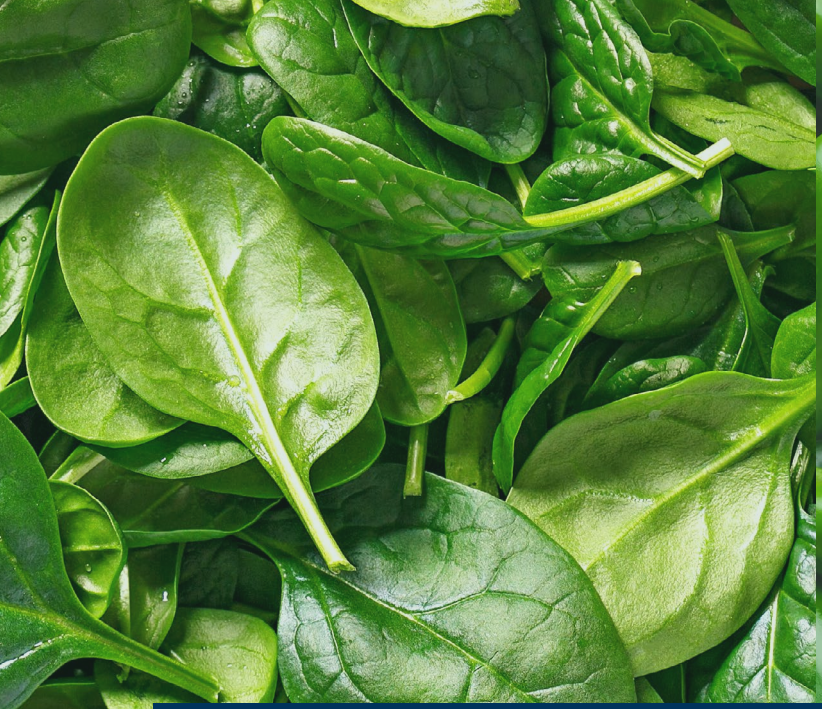


What the Past Tells Us About the Future of FSMA 204

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Introduction

Once the deadline for complying with FDA's Food Traceability Rule, FSMA 204, is here and the new requirements are in place, what's next? What will life look like for the food industry?

Companies covered by this rule established by the FDA Food Safety Modernization Act (FSMA) are now laser-focused on meeting the January 20, 2026 compliance deadline. However, not all companies have welcomed the new requirements, even though the fresh produce industry has been plagued for decades by traceback investigations that proved ineffective.

Supporters of the rule in both the public and private sectors believe the overarching transparency that traceability provides will inspire companies to strive toward more enlightened approaches to improve food safety. Some view improved traceability as an opportunity to create operational efficiencies and reduce waste.

However, others see it as just another cost of doing business in a highly competitive, generally low-margin industry.

This is a good time to take a step back and look at the big picture. It's important to remember why FSMA 204 became law, to look back at the outbreaks that have been so devastating to both the food industry and the people they serve. A measure of the potential future impacts of FSMA 204 might be to re-examine our past.

So, let's ask this question: How might the outcomes of previous outbreak investigations have been improved if FSMA 204 had already been in place and the companies involved compliant? We'll look retrospectively at four seminal fresh produce outbreaks with this question in mind.

You'll see that the outcomes might have been significantly improved, with FSMA 204 potentially reducing the impact of each outbreak on human health and on consumer faith in the safety of these commodities.

The "Three-Legged Stool" of Outbreak Investigations

Actually, traceback is only one leg or center of activity of what is known as the three-legged investigative "stool" of an outbreak investigation. So, before we examine the potential impact of FSMA 204, it is important to understand what an effective and efficient outbreak investigation engenders and what role traceability plays.

First leg of the stool
Identification

Logically, the first leg of the "stool" is to identify the likely causative foods involved. This is usually accomplished using questionnaires or by directly interviewing people who were made ill about what they ate just before becoming ill and where they ate it. Epidemiologists use this information to identify the intersections between common foods consumed by victims and the locations where they were purchased.

Second leg of the stool
Traceback to the source

Once prospective causative foods are identified, traceback to the source can follow. Tracing back (and forward) through the supply chain often permits public health officials to determine the likely source of the contamination and assess the severity of the risk to public health.

Effective traceability also helps shape the efficiency and effectiveness of an investigation in ways that benefit both consumers and the produce industry. Effective and efficient traceability can:

- Narrow the scope of recalls and avoid broad consumer "do not eat" alerts that shut down entire segments of the industry and often erode consumer confidence in fresh produce.
- Provide more timely and accurate identification of specific companies and brands involved and preserve customer and consumer equity for companies and brands not involved.
- Permit identification and supply chain tracking of single ingredient products, e.g., green onions and secondary, more complex consumer products like pizzas and soups where the same green onions can be used as ingredients and impact a broader segment of consumers.
- Enable more timely investigations increasing the likelihood of the timely removal of contaminated products from the marketplace and protecting consumer health and finding the true root cause of the contamination so that repeat or similar events can be more effectively prevented in the future.

Third leg of the stool
Microbiological testing

Running all through epidemiological and trace activities is the third leg of the "stool," microbiological testing. The aim is to isolate the responsible pathogen(s) from the victim and to link them to areas in the suspected production environment and in related products thereby achieving the desired "trifecta" of patient, food and production location.

Missed Opportunities

In truth, the majority of foodborne illness outbreaks are never fully resolved, and the "three-legged stool" ideal is not always achieved. Often, the inability to quickly perform a traceback to the source precludes facility or farm inspection and microbiological testing. These should be viewed as missed opportunities to learn what happened to cause product contamination, why it happened and explore how it can be prevented from happening again.

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4 Impactful Outbreaks of Years Past

As we review these four historical outbreak investigations it is important to keep in mind that successful traceback is almost always about obtaining actionable, accurate information quickly. We will use that simple perspective to weigh the impact that FSMA 204 might have had on the investigation, using the three-legged investigative stool as a scorecard.

1. **2006 E. coli outbreak linked to fresh spinach**
2. **2008 Salmonella outbreak linked to fresh peppers**
3. **2017-2018 E. coli outbreak linked to romaine lettuce**
4. **2011 Listeria outbreak linked to Rocky Ford cantaloupe**

In September 2006, an outbreak of *E. coli* O157:H7 was linked to the consumption of fresh bagged spinach.

Impact

Illnesses	Hospitalizations	Deaths	Serious diseases or illness
205	102	4	31 cases of kidney disease or Hemolytic Uremic Syndrome (HUS)

Economic impact on growers: $75 million

An industry shut down

Though there had been a number of fresh produce related outbreaks and recalls leading up to 2006, for many in the industry, this "spinach crisis" was a watershed moment. On September 14, 2006, FDA issued its first-ever consumer alert instructing consumers not to eat fresh spinach; essentially shutting down the entire U.S. fresh spinach industry. Commodity and bagged spinach products were removed from store shelves, spinach sat unharvested in the fields, processors halted operations, and workers were sent home. Some consumers stopped buying leafy greens altogether and the industry became the butt of jokes on late-night television for weeks.

Western Growers, a trade association representing many leafy greens growers in California (where 75% of the country's leafy greens are grown), estimated the outbreak cost growers upward of $75 million. Of course, this estimate omits costs associated with lost wages by workers who were displaced along the supply chain.

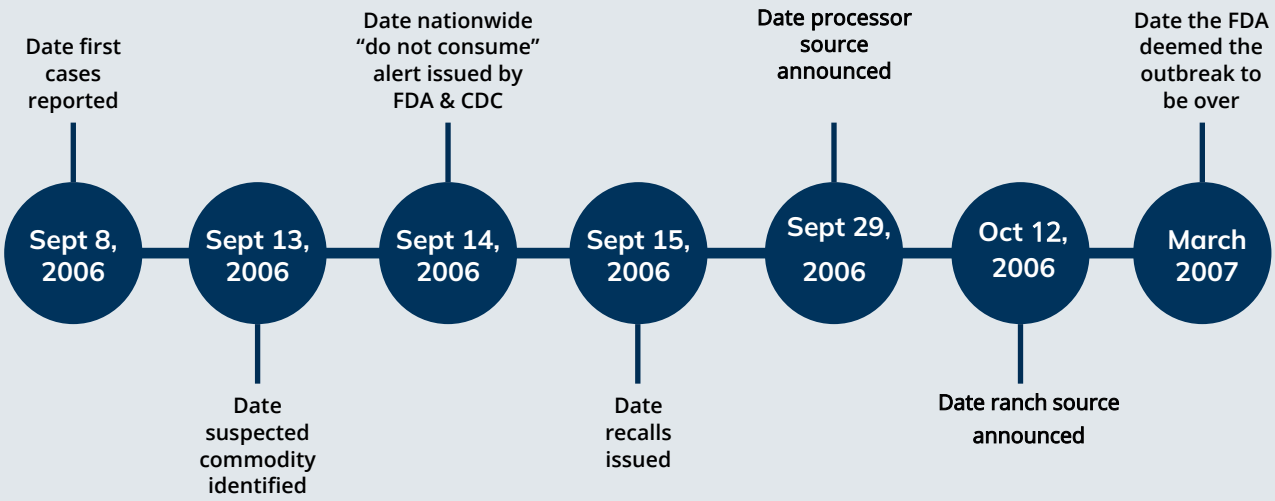
Several studies have shown that consumers drastically reduced their expenditures on spinach products but tended to shift those expenditures to other replacement vegetables. Many in the industry feel that the spinach market took nearly a decade to recover to pre-outbreak levels.

A circuitous route to identifying the source

Would the investigation or the outcomes from the 2006 "spinach crisis" have been different if FSMA 204 had been in place? First, it must be cautioned that we have the benefit of looking back 17 years with the accumulated knowledge resulting from the FDA investigation in 2006-2007 and the experiences gained since that time. Focusing on the role of traceability (or lack thereof) in a 2016 10th anniversary retrospective article, Dr. Bob Brackett, Director of FDA CFSAN in 2006, is quoted as saying, "we knew it was bagged spinach but had no idea whose it was or where it was coming from".

With that as a starting point, a review of the outbreak timeline is instructive in assessing the potential impact of FSMA 204. FDA and CDC were alerted by the Wisconsin Department of Public Health (DPH) to four HUS cases in their state on September 8, 2006, and by September 12th, the PulseNet System matched *E. coli* O157:H7 DNA fingerprints from patient samples in Wisconsin to patient samples from other states. On September 13th, the Wisconsin and Oregon DPHs alerted CDC and FDA that their epidemiological studies led them to suspect bagged spinach as the cause of these cases. With the epidemiological leg of the investigative "stool" indicating bagged spinach as the causative food, the growing number of cases and the severity of *E. coli*-related illness in mind, the FDA and CDC issued a "do not consume" alert on September 14, 2006. The inability to identify specific suppliers in these early days of the investigation essentially forced FDA to issue a broad nationwide alert covering all spinach products, effectively shutting down the spinach industry.

The investigation timeline



Patient interviews help narrow the investigation, resulting in voluntary recalls

Information gained by patient interviews pointed to several potential processors, finished product brands and points of sale (retail and foodservice outlets) where consumers ate or purchased spinach. Using this data, state DPH investigators contacted potential source companies and on September 15th the first of at least eight companies launched voluntary recalls of spinach and spinach-containing products. In effect, this marked the first real advance of the traceback leg of the investigative "stool" though the lack of standardized traceability systems precluded a focused approach and supply chain records from initially identified companies would prove exceedingly difficult to navigate manually. By September 24th, the Utah DPH announced that isolates from a bag of spinach recovered from a patient matched the outbreak *E. coli* O157:H7 strain. Pennsylvania joined with a similar announcement on September 26th. Ultimately, there were 45 packages of left-over spinach

collected from case patient households from 14 states, 37 were produced by a single processor and 34 were of the same brand, with 17 of these having the same production codes. Thirteen out of 44 bags of spinach tested had a matching DNA fingerprint to the outbreak strain of *E. coli* O157:H7. This breakthrough permitted FDA to announce on September 29th the name of a processor in San Juan Batista, CA that manufactured the products, a single production date (August 15th), shift ("A"), and a brand.

Trace-forward activities kicked off

In effect, the recovery of these bags of product from patients kick started trace forward activities from the processor in California to retail and foodservice outlets across the nation and traceback efforts to identify specific ranches and fields where spinach was grown and harvested during the early to mid-August production period that lined up with the outbreak of illnesses. The traceback led FDA and CA DPH to investigate and take environmental samples from four different ranches across three counties.

On October 12, 2006, they announced that a single ranch in San Benito County, CA was the source of the raw spinach responsible for the outbreak based on the traceback and the identification of the outbreak *E. coli* O157:H7 strain in environmental samples from that ranch.

So, how could FSMA 204 have made a difference in 2006 had it been in place?

It took a month from the issuance of the FDA "do not eat" alert to the announcement of the source of the outbreak. Absent effective traceability the alert was national and covered all spinach producers and products. But almost from the beginning, the epidemiology pointed to bagged spinach and in fact investigators had a bag positive for the outbreak strain from Utah by September 24th.

Had FSMA 204 been in place, it seems like investigators could have used the patient data to locate the retail venue where the bag was purchased. Under FSMA 204, the retailer would need to produce the receiving invoice from the supplier within 24 hours. Cross checking, compliant with FSMA 204, the bag of spinach would have had a product code which would identify the supplier and again, within 24 hours, identified traceback to the farm where the original raw spinach was harvested and the date of production. The required FSMA 204 spreadsheet capturing key data elements and critical tracking events would have supplanted the laborious and manual review of non-standardized documentation to arrive at the identification of the manufacture date and process line at least a full week (August 15th during shift A8) before the actual September 29th date.

While FSMA 204 may not have precluded the nationwide "do not eat" advisory on September 14th, it certainly would have permitted a follow up communication from FDA and CDC a few days later based on the recovery of packages from victims, the linkage of the outbreak strain to those bags and the data spreadsheet required by 204 to drastically narrowing the recall and consumer warning to a specific company and even a specific farm and field.

Missed opportunities for clear communications

Additionally, access to FSMA 204 data would also have permitted both industry and the regulatory community to communicate with consumers about the process used to identify the source of the contamination and the safety of the remainder of spinach and leafy greens suppliers. Instead, confused communications flooded the media and severely damaged the credibility of all parties involved. The prolonged investigation and ominous communications embedded a perception by consumers that spinach was unhealthy which took a decade to overcome.

It is not clear that an earlier identification of the processor and ranch would have fundamentally impacted the subsequent search for a root cause of the outbreak. Indeed, by the time the outbreak was detected, the subsequent epidemiological data suggested the number of cases was declining and the fields had been harvested and the ground ready for the next crop.

Learnings and proactive action

There were a number of valuable learnings emanating from the investigation that have shaped subsequent food safety research priorities and food safety audit practices. The 2006 outbreak resulted in the formation of marketing agreements committed to a common set of food safety metrics in California and Arizona. It was also a driving force in the development of 2011 Food Safety Modernization Act (FSMA) and the all-important Produce Safety Rule. While the CDC declared the outbreak over on October 6, 2006, and FDA issued its final report in March 2007, the human tragedy of the 2006 spinach crisis remains fresh in the minds of the industry and its impact can still be felt today in any discussion on food safety and traceability.

The three-legged investigative stool:

Identification: A suspected food was identified five days after illnesses were first reported. Post FSMA 204, the epidemiological process would be much the same.

Traceback to the source: It took a month after the "do not eat" order for the source of the outbreak to be announced. Post FSMA 204, the lot code associated with the bagged spinach would have identified the supplier, as well as the farm where the original raw spinach was harvested and the date of production

Microbiological testing: Isolates from a bag of spinach recovered from a patient were first matched to the outbreak strain 16 days after illnesses were first reported. Post FSMA 204, rapid traceback would have facilitated earlier testing of farms and facilities.

The causative food

45 Packages of Spinach

34 Same brand

14 States

14 Same production code

37 Produced by a single processor

2008 – Salmonella in Tomatoes then Peppers Triggers the need for the Produce Traceability Initiative.

In 2008, an outbreak of salmonellosis resulted in 1,442 reported illnesses, 286 hospitalizations and 2 deaths across 43 states, the District of Columbia, and Canada. From the perspective of 15 years later and the benefit of hindsight, it seems like from the moment the outbreak was detected and reported by public health officials in New Mexico on May 22, 2008, the investigation was plagued with epidemiological and traceback complexities that led to confusion and frustration with public health agencies, the produce industry, and consumers.

Impact

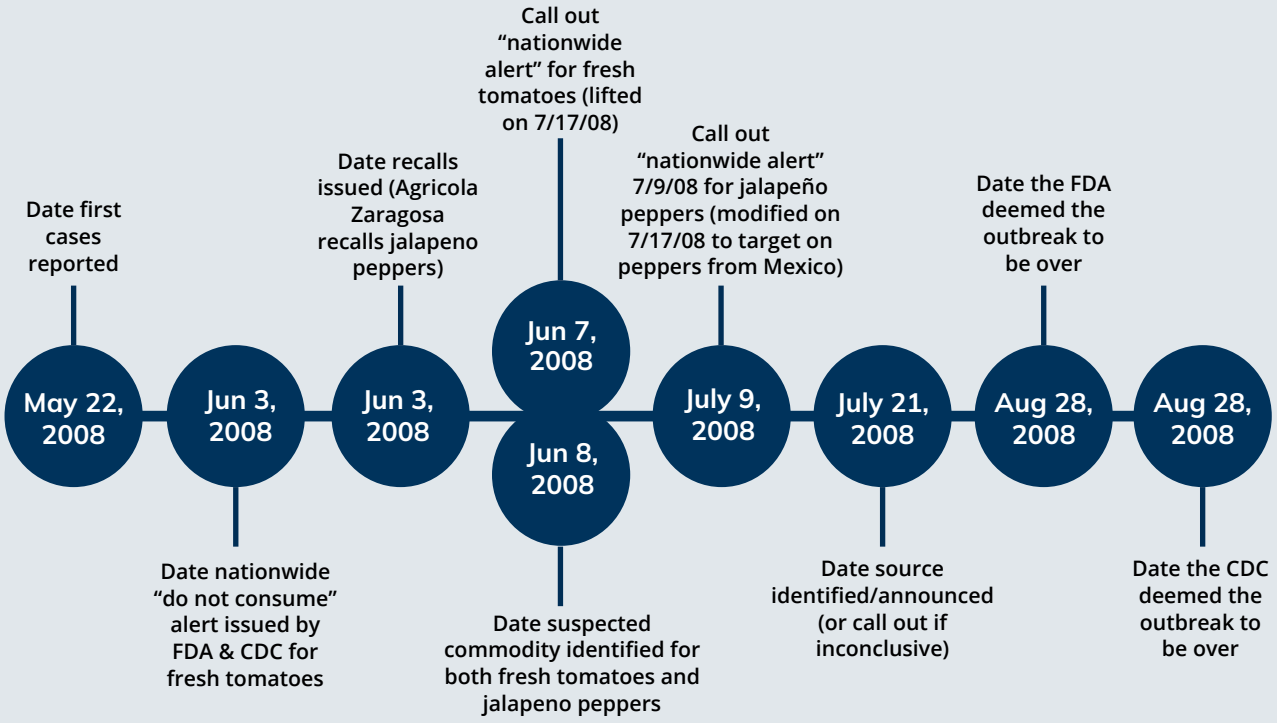
Illnesses	Hospitalizations	Deaths
1,442	286	2

Economic impact on growers: $120 million

Again, a brief examination of the outbreak timeline brings context to today's discussions on FSMA 204 and the issues it addresses. By May 23, 2008, CDC, using PulseNet, identified cases in Colorado and Texas of *Salmonella Saintpaul* that had DNA fingerprints matching those reported in New Mexico. Initial case control studies pointed to consumption of fresh tomatoes at restaurants as the mode of infection. By June 3, 2008, CDC and FDA issued a consumer "do not eat" advisory for Texas and New Mexico for fresh tomatoes. With the rate of reported illnesses geographical spread expanding rapidly, the alert went national on June 7th. As additional clusters of *Salmonella Saintpaul* illness were identified, new case control studies were initiated by CDC and various states leading to different results.

A study in mid-June landed on a significant association between illness and the consumption of salsa with canned jalapeño peppers, but not fresh tomatoes. Another case control study in late June 2008 associate illness with the consumption of Pico de Gallo, tortillas, and fresh salsa. Still others later that month in Minnesota and Colorado pointed to jalapeño peppers as the causative food. On July 9, 2008, a nationwide "do not eat" advisory was issued by CDC and FDA on jalapeño peppers. On July 17th, FDA lifted the tomato advisory followed by a July 30th warning modified to "do not eat" peppers from Mexico.

Timeline



Tracing the source – hint: it wasn't the tomatoes

Of course, simultaneous to the epidemiology, investigators were working to trace tomatoes and/or peppers to the source. From the outset, as investigators attempted to work back from patient information on foods consumed and restaurants where they ate prior to becoming ill, they were hampered by inconsistent and incomplete food safety and supply chain documentation. In the initial stages of the traceback focused on fresh tomatoes, investigators could not find a convergence to a single packer, distributor, or growing area. No positive *Salmonella Saintpaul* results were ever found from tomatoes taken from ill patients or the marketplace. As the epidemiology began to point at jalapeño peppers, investigators began working on an illness cluster from a Texas restaurant chain supplied by a distributor who, in turn was supplied with peppers from two farms in Mexico.

On July 21, the FDA announced they had isolated the outbreak strain of *Salmonella Saintpaul* from a jalapeño pepper taken from the Texas distributor who sourced the pepper from the first farm, designated "Farm A". Farm A also grew serrano peppers and Roma tomatoes. Subsequent investigations of Farm A and a second farm, "Farm B" did not turn up any positive environmental samples from Farm A but did uncover positive *Salmonella Saintpaul* samples in an irrigation pond and in serrano peppers grown on that farm. Farm B also grew jalapeño peppers but did not grow tomatoes. Both Farm A and B supplied jalapeno and serrano peppers to the Texas distributor. The outbreak was declared "over" on August 28, 2008.

Would FSMA 204 requirements for traceability have made a difference had they been in place in 2008?

The obvious answer is "yes."

Had investigators had access to receiving records required by FSMA 204 from the restaurants associated with illness clusters within 24 hours and subsequent KDE and CTE traceability documentation from distributors and wholesalers, the time to identify the source of the contaminated peppers could have been shortened substantially putting investigators on the ground to obtain samples and confirm the presence of the pathogen much sooner. The initial epidemiology that pointed investigators to fresh tomatoes would not have been impacted, however it is conceivable that with the traceability tools afforded by FSMA 204, FDA and the states may have been able to eliminate tomatoes or more specifically tomatoes from Florida and Georgia (which were in harvest during the time of the outbreak), more quickly from consideration as they subsequently found no points of convergence after sifting through random, often incomplete, often handwritten traceability documentation from end receivers and distributors.

The tomato industries in Florida and Georgia suffered approximately $120 million in damages because of the likely misidentification of fresh tomatoes as the causative food in the outbreak. It is difficult to estimate what fraction of that cost might have been avoided if the alert had been withdrawn in early to mid-June as opposed to mid-July. However, the ability to communicate clearly and definitively to consumers what had happened, and the

traceability data used to remove them from responsibility for the outbreak might have muted consumer's loss of confidence and shortened the timeline for market recovery.

A milestone for a fragmented supply chain lacking standards

The *Salmonella Saintpaul* outbreak in 2008 remains a milestone in traceability. For the first time relative to the produce industry, the difficulties CDC, FDA, and state DPH's had owing to the complexities of the fresh produce supply chain – multiple suppliers of the same commodities, multiple farms, packers, repackers, distributors, wholesalers, retailers, chain restaurants, smaller "mom and pop" restaurants, multiple countries and regulatory frameworks, and coordination of state departments of health and data analysis came into view in a very public way. Efficient traceback was nearly impossible as each stop in the supply chain had their own approach to tracing products and a trail of fragmented, often incomplete records that FDA struggled to decipher to create a traceback and forward from source to end-user. The industry disruption and economic and reputational damage of this outbreak coupled with the lingering impact of the 2006 *E. coli*/spinach outbreak was the catalyst for industry efforts to develop product traceability standards across the supply chain.

The development of PTI

In 2009 the Produce Traceability Initiative (PTI) was formally organized with broad supply chain support to develop case-level traceability across the fresh produce supply chain. While PTI's achievements are many, especially at the grower/processor level, its full supply chain implementation was never achieved assuring the final FSMA rules signed into law in 2011 would mandate improved traceability – today's FSMA 204. Core elements of the PTI approach live on in FSMA 204 in terms of tracking and capturing data at key transition and transformation points in the supply chain and the concept of standardized lot codes that captures the identity of the lot number, source company identity, production date and other important information that permits rapid, electronic tracking of product as it moves through the supply chain.

The three-legged investigative stool:

Identification: The initial epidemiology that pointed to fresh tomatoes would not have been impacted, but the traceability tools afforded by FSMA 204, FDA and the states may have been able to eliminate tomatoes more quickly from consideration.

Traceback to the source: Efficient traceback was hampered by inconsistent ways of tracing products and incomplete records that were often handwritten. FSMA 204 establishes a consistency and transparency with an established way to capture and share data.

Microbiological testing: Testing eventually identified jalapeño peppers as the causative food. Post FSMA 204, rapid traceback would have facilitated earlier testing of farms and facilities.

The causative food

Serrano and Jalapeño Peppers

43 States

2 farms in Mexico

1 Distributor

1 Restaurant Chain

2017-2018 *E. coli* O157:H7 outbreak associated with romaine – yet another tipping point?

From early November through to mid-December 2017, FDA and CDC investigated an outbreak of *E. coli* O157:H7 that ultimately sickened 25 people across 15 states; 9 required hospitalization, 2 developed HUS syndrome, and one died. In January 2018, FDA and CDC declared the outbreak over and despite an extensive traceback effort, no source was identified. FDA concluded the likely causative food was leafy greens (including romaine lettuce) but could not link ill patients to a common supplier, distributor or point of sale. Public health investigators were additionally stymied because no product was recovered from patient households with identifying brands or product codes and the large number of potential suppliers for leafy greens selling products into retail.

Impact: USA 2017

Illnesses	Hospitalizations	Deaths
25	9	1

Serious diseases or illnesses: 2 cases of Hemolytic Uremic Syndrome

Same thing happened in Canada, but still no resolution

At the same time, The Canadian Public Health Agency was investigating an *E. coli* O157:H7 outbreak with nearly identical onset dates to the one being investigated by FDA in the US. This outbreak involved 42 cases across 5 eastern Canadian provinces that resulted in 17 hospitalization and one death. Though controversial at the time, Canada linked the illnesses directly to romaine and stated that "most of the individuals that became sick reported eating romaine lettuce before illness occurred". The Canadian Food Inspection Agency (CFIA) tested romaine samples taken from retail and foodservice outlets without finding a positive sample. But interestingly patient samples from Canada and the US yielded *E. coli* O157:H7 isolates that were closely related genetically indicating that the two outbreaks may actually be one outbreak with a broad geographic spread. In any event, the Canadian investigation stalled just as the U.S. efforts had when no common supplier could be linked to the ill patients.

Impact: Canada 2017

Illnesses	Hospitalizations	Deaths
42	17	1

Again in 2018

In a case of history repeating itself, on November 1, 2018, FDA's Coordinated Outbreak Response and Evaluation (CORE) team began investigating a cluster of 17 *E. coli* O157:H7 cases. By the week of November 13th, whole genome sequencing analysis had linked the 2018 *E. coli* O157:H7 strain genetically to the one that had caused illnesses in the US and Canada in 2017. Based on the investigation in 2017, CDC hypothesized the 2018 outbreak vehicle was romaine. Ultimately, the 2018 outbreak impacted 17 states in nearly the same geographical distribution pattern as the outbreak of the previous year. Fortunately, there were no deaths in 2018.

Impact

Illnesses	Hospitalizations	Deaths
62	25	1

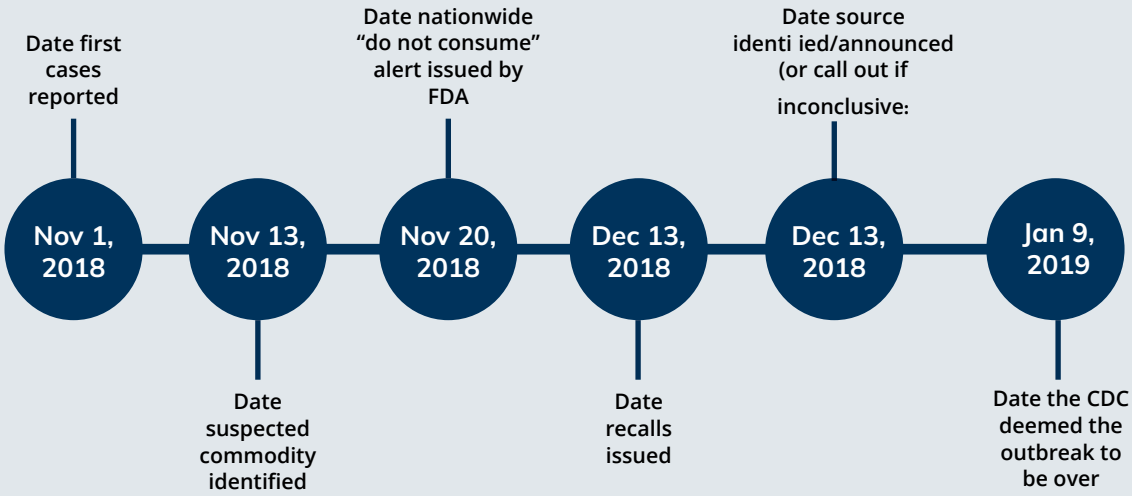
Financial losses by growers, processors and retailers:	**$70 million**

A halt on romaine

Given the frustrations of the previous year and facing the same hurdles to effective traceback in 2018, FDA asked producers to stop shipping romaine, retailer and foodservice providers to pull the products from their shelves and kitchens and advised consumers "not to eat" romaine on November 20, 2018. The impact in the media and within the industry was immediate. Coming on the heels of the 2017 outbreak that had ended without closure and the unrelated spring 2018 *E. coli* O157:H7 outbreak associated with romaine grown in the Yuma region of Arizona, which also ended without a definitive root cause, the response from regulators, industry, consumers, and media was one of frustration and even anger. Yet again, the "do not eat" advisory crashed the romaine markets around the country. Estimates of the financial loss from the 2018 outbreak directly incurred by growers, processors and retailers reached $70 million with salad processors bearing the brunt of those losses at $55 million. Overall, the societal losses across the supply chain resulting from the 2018 outbreak have been estimated at $275 to 343 million.

By late November and into early December 2018, FDA continued their efforts to narrow the scope of the industry-wide alert. By December 6, 2018, investigators closed in on the central coast of California, but the outbreak still could not be explained by a single farm, grower, harvester, or distribution center. Indeed, the traceback from four restaurants in three states lead to 10 distributors, 12 growers and 11 different farms as potential sources of the contaminated product. However, any traceback investigation is really multiple investigations examining different "legs" of inquiry simultaneously and on November 23, 2019, FDA and CDFA began visiting farms and cooling facilities in California to collect product and environmental samples, including water samples. But, as of December 6th, no positives for the outbreak strain of *E. coli* had been found, albeit the results from water samples being analyzed by CDC were still pending. By December 13th, FDA refined the scope of the investigation narrowing the list of California counties that might have supplied the tainted romaine to Monterey, San Benito, and Santa Barbara; exonerating Santa Cruz, San Luis Obispo, and Ventura counties and freeing Imperial and Riverside counties (which were just coming into harvest) as well as other romaine production areas in Florida, Arizona, and Mexico to begin shipping romaine. Equally important, CDC and FDA reported that a sediment sample from an agricultural water reservoir on a single ranch in Santa Barbara County had tested positive for *E. coli* O157:H7 and that strain was a genetic match to the outbreak strain. The grower, who had stopped romaine shipments on November 20, 2018, recalled other fresh vegetables (red and green leaf lettuce as well as cauliflower) that may have come in contact with the water from the reservoir. On January 9, 2019, the CDC reported the outbreak was over.

The investigation timeline



Would FSMA 204 have aided investigators if it had been in place in 2017 and 2018?

Almost certainly.

This was a two-year ordeal that highlighted the industry's lack of supply chain traceability and brought into focus not just the traceability inadequacies faced during this outbreak but reinforced earlier traceability failures from previous outbreaks going back over two decades. The FDA repeatedly stated that they just could not "go the last mile," i.e., the traceback broke down between the distribution center and the various points of consumer interaction, e.g., restaurants and retail stores. In a presentation summarizing the 2017 and 2018 outbreaks, FDA CORE listed their challenges:

- Lot information was not consistently available at the point of service. When lot codes were present, it was often unclear how they were formatted and how to discern the original grower, pack dates, locations, etc.
- Raw products were often comingled such that raw products from multiple farms were used to make a single final product making it difficult to identify responsible farms.
- The records or traceability documents including lot codes were not in any standard format and may change at each point of receipt in the supply chain. This made it difficult to decipher the movements of raw and finished products and was very time-consuming.
- Timing is always critical during a traceback. Traceback is a step-by-step process, i.e., data is collected, analyzed, understood and then the investigation can move on to the next step in the supply chain journey. In this 2017-2018 outbreak, the data were not complete or difficult to understand and follow from step to step.

- Multiplicity of products that contain or "are" romaine caused confusion in industry and consumer communications. Romaine can be sold as a whole head, as a trimmed heart, trimmed/ready for process, as a simple chopped salad or in a plethora of salad blends and kits. Understanding which products were involved in the advisory and recall in 2017 and then in 2018 was difficult for regulators, consumers and the industry.
- Product labels were often unclear and difficult for regulators and consumers to understand. Individual companies often have multiple brands and/or co-pack for other brand owners adding another level of difficulty.

The challenges listed by FDA CORE in summarizing the 2017-2018 *E. coli* O157:H7 outbreak line up pretty well with the deficiencies observed in nearly all outbreaks and recalls associated with fresh produce and frankly shape the requirements of Rule 204 that followed as a final published rule exactly 5 years after this outbreak, on November 15, 2022. Specifically, had the points of sale in 2017 been able to supply FDA with the KDEs (receiving documents identifying the suppliers) required by FSMA 204 when the epidemiology led investigators to their door within 24 hours, it is possible that the 2017 investigation might have been able to narrow the scope of their investigation to a specific grower and farm and subsequent root cause analysis may have led to the agricultural water reservoir and perhaps other locations on that farm (or others) a year earlier and preventive actions taken that could have reduced the chances of the outbreak in 2018.

The three-legged investigative stool:

Identification: Slowed by the fact that product recovered from points of service often lacked identifying brands or product codes. Post FSMA 204: Traceability Lot Codes will uniquely identify the food and the required records.

Traceback to the source: Greatly hampered by inconsistent lot codes, unclear labels and incomplete data. Post FSMA 204: Key Data Elements collected at Critical Tracking Events will greatly speed the location of the source.

Microbiological testing: Eventually tied outbreak strain to a sediment sample from an agricultural water reservoir. Post FSMA 204: Rapid traceback would have facilitated earlier testing on farms.

The causative food

Leafy Greens, Romaine

15 States

5 Provinces in Canada

10 Potential Distributors (exact number unknown)

11 Potential Farms (exact number unknown)

$275-$343 million in losses

12 Potential Growers (exact number unknown)

2011 *Listeria* outbreak associated with Rocky Ford cantaloupes – a glimpse into the future?

At this point, we will jump back to 2011 to review an outbreak investigation that is recognized for its effectiveness. In 2011, an outbreak of listeriosis was associated with the consumption of fresh cantaloupe. This outbreak remains one of the deadliest ever in the U.S. resulting in illnesses and deaths across 28 states.

Impact

Illnesses	Hospitalizations	Deaths
147	143	30

Financial losses in sales: $4 million

Traceability stands out as a success

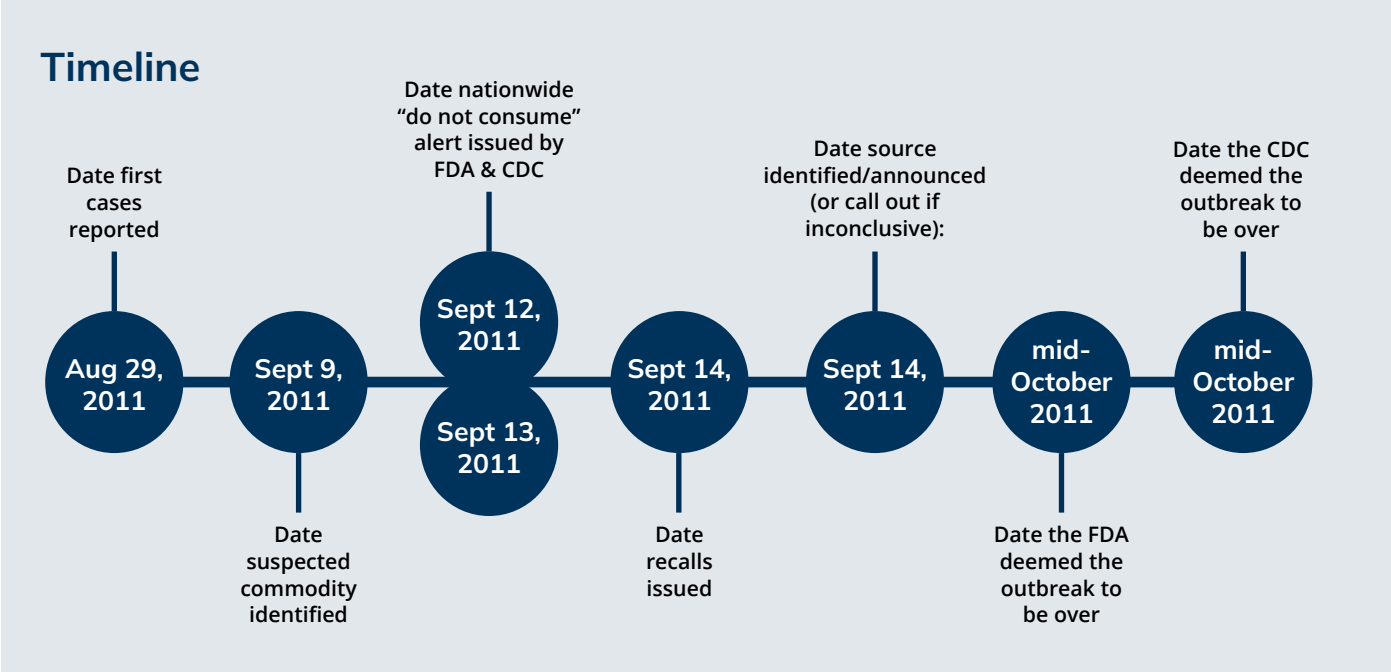
The severity and the tragedy of the human toll this outbreak took aside; this outbreak stands out from the three described above with respect to traceability because of how quickly all the elements of the three-legged stool fell into place, i.e., epidemiology led directly to the causative food and points of sale to consumers, the traceback quickly identified points of convergence where victims purchased the cantaloupes from retailers that sourced cantaloupes from a specific grower and the outbreak subtypes of *Listeria monocytogenes* (Lm) were found on products, in patient's samples and in swabs from the grower's packing operation. Absent FSMA 204 tools, the strong epidemiology still fueled an effective traceback and the microbiology confirmed its efficacy.

The timeline for the 2011 Lm outbreak associated with cantaloupes shows a much more effective investigation than those already discussed for spinach and romaine *E. coli* O157:H7 outbreaks and the pepper, tomato *Salmonella Saintpaul* event. On September 2, 2011, the Colorado Department of Public Health and Environment (CDPHE) notified the CDC that seven cases of listeriosis had been reported since August 29, 2011. Initial microbiological analysis of patient samples indicated three different genetic fingerprints of *Listeria monocytogenes* (Lm). Four days later on September 6th, the PulseNet system identified additional patients with the outbreak strains in Nebraska and Texas.

Initial interviews with patients revealed all 7 patients had eaten fresh cantaloupe and 3 reported eating a specific regional type of cantaloupe, known as Rocky Ford cantaloupes, grown in Colorado. With three states now involved, CDC opened a multistate investigation on September 7th. On September 8, 2011, CDC asks states to use the supplemental questionnaire created by CDPHE to learn more about cantaloupe eaten by ill persons and FDA began its investigation using the data from patient interviews and questionnaires to identify sources of cantaloupe eaten by ill persons. Cantaloupes were collected for *Listeria* testing from retail locations where ill persons reported buying cantaloupes.

Overall, 134 of 144 patients questioned reported eating cantaloupe during the month leading up to their illness and 113 out of 118 patients remembering where they purchased their melons named major retail chains and 20 remembered a specific brand grown only in Colorado.

By September 9th, CDPHE announced that cantaloupes were the likely cause of the reported listeriosis outbreak and issued a “do not eat” warning to high-risk Colorado residents. The next day, September 10th, informed by the data collected from the epidemiological evidence and preliminary traceback information, FDA and CDPHE visited a Colorado farm known for growing and distributing the regional cantaloupe variety implicated by the epidemiology. An inspection was performed, product and environmental samples taken, and the broker that distributed Rocky Ford cantaloupes notified retailers to remove Rocky Ford cantaloupes from shelves. By September 11, 2011, the preliminary traceback investigation pointed to Rocky Ford cantaloupes and retail locations where ill patients purchased them were contacted. Cantaloupe samples from patients and retail locations were found to be positive for the outbreak strain of Lm. On September 12th and 13th, the CDC and FDA notified consumers nationwide of the outbreak investigations and warned them “not to eat” cantaloupes. By September 14th, FDA announced a product recall and narrowed the warning to consumers to whole Rocky Ford cantaloupes from a specific Colorado farm. From this point forward, the investigation activity evolved to focus on the microbiological “leg of the stool” and by the end of September, outbreak strains of Lm found in patients were also detected in environmental packinghouse and equipment samples and product samples taken at the farm that grew the cantaloupes. The traceback segment of the investigation resulted in additional product recalls as some regional processors had used Rocky Ford cantaloupes from the implicated farm to manufacture a variety of fresh-cut melon products.



Source identification only took two weeks

From discovery on August 29th to the CDC and FDA definitively identifying the causative food and finding the farm responsible and recalling the product from retail shelves took two weeks. The final FDA report was issued in mid-October though the ramifications of the outbreak live on today in the form of industry programs on *Listeria* control and research. Overall, the outbreak associated with Rocky Ford cantaloupes resulted in nearly a $4 million decrease in cantaloupe sales in October 2011 compared to the previous two October sales levels. The ability of CDC and FDA to create clear and concise messaging around the variety and production region and get to a specific grower quickly gave consumers the opportunity to understand what was happening, gauge their risk, and divert their melon spending to other types of cantaloupes and melons.

So, would FSMA 204 have made a difference with this outbreak?

In some ways, the 2011 outbreak associated with Rocky Ford cantaloupes is a rudimentary example of what traceback investigations can look like when FSMA 204 takes effect in January 2026. This outbreak, in a way, is a black swan event; it had very specific characteristics that obviated the need for data-driven traceability. That is not to diminish the work of the investigators that worked hard and quickly to find the source of contamination in this incident and curtail its impact, especially given the pathogen was Lm, an organism with often severe consequences. But let's look at the outbreak closer and consider:

- Patients/consumers recognized the distinctive cantaloupe variety/type (Rocky Ford) they consumed.

- The cantaloupes were produced in a specific region in one state with relatively few growers.
- At the time of the outbreak, fresh produce was not viewed as a typical vehicle for listeriosis, yet fresh cantaloupe was included in the CDC questionnaire used with potential victims and CDC and CDPHE followed up with an augmented questionnaire quickly to glean more information that permitted them to narrow the focus of the subsequent investigation.
- The time from consumption to onset of illness is typically much longer with *Listeria* infections than *Salmonella* or *E. coli* thus sometimes making it harder to identify the beginning and end of an outbreak, but CDPHE detected the outbreak early and reported it to CDC thus jumpstarting the investigation nationally.
- Several Ill patients (including some of the initial cases) had remining cantaloupes still in their possession at home available for testing. The same happened with retailers and the grower/packer.
- The broker had receiving documentation for cantaloupes from the grower and shipping records for retailers they had distributed the product to permitting a relatively straightforward process of contacting the stores and removal of product as well as identifying the grower.
- The outbreak was detected near the end of the Colorado cantaloupe season and the farm responsible was actually just finishing the season and still operational facilitating meaningful observations and environmental sampling by investigators. Often, by the time the onsite inspection occurs, considerable time has passed, and the season may indeed be over or environmental conditions have changed significantly.

A rapid investigation led to rapid communication

Undoubtedly, considering the severity of illness perpetrated by the Lm outbreak strains, the rapid pace of the investigation enabled by the information the state and federal public health agencies were able to obtain very early in the investigation, helped get contaminated product out of the marketplace and permitted timely consumer communications. Successful outbreak investigations are always dependent on getting information to build as much of the "three-legged stool" as fast as possible. Examining this outbreak, good fortune and hard work by public health professionals led to a successful investigation and ultimately to a determination of a root cause for the contamination.

Looking at the information generated in the early stages of this investigation, it checks many of the boxes FSMA 204 mandates, shipping and receiving documentation by the distributor, identification of the grower and ultimately the fields and packinghouse of the responsible party. Clearly, the 2011 listeriosis outbreak associated with cantaloupes did not turn based on electronic records in an organized spreadsheet produced within 24-hours as FSMA 204 requires, but the relative simplicity of the supply chain and the limited number of companies involved offset the usual issues with traceability in outbreak investigation. Once the epidemiology overwhelmingly identified the causative food it fueled rapid linkage from patients

to retail outlets back to the broker and on to a single grower/packer quickly. FSMA 204 probably would not have greatly improved the investigation speed in this case, but this outbreak does provide us with a glimpse of the potential to better protect public health and limit unwarranted damage to the produce supply chain when traceback can be accomplished effectively and efficiently.

The three-legged investigative stool:

Identification: Rapid in this case because patients recognized the distinctive cantaloupe. Post FSMA 204: Identification of the causative food would be just as rapid in more complex situations.

Traceback to the source: The simplicity of the supply chain and the limited number of companies involved offset the usual issues with traceability. Post FSMA 204: Traceability will be as effective as this, if not more, for both simple and complex supply chains.

Microbiological testing: Confirmed presence of outbreak strain on Colorado farm. Post FSMA 204: Testing will be as effective, if not more, with rapid traceback.

The causative food

Cantaloupe

28 States

1 Grower

$4 million in losses

In Summary

The first three outbreaks summarized here were landmarks for the fresh produce industry. The outbreak tied to bagged spinach in 2006 marked the first time that FDA issued a nationwide consumer alert advising consumers not to eat fresh spinach.

In 2008, another national alert was issued to keep consumers from eating fresh tomatoes. Only this time, it was actually jalapeno peppers that were making people sick and a second national alert was issued.

In 2017 and 2018, there were outbreaks associated with romaine lettuce, with another national alert issued over the Thanksgiving holiday that consumers should not eat romaine lettuce.

Commonalities stressing the importance of traceability

In each of these cases, industry lost hundreds of millions in revenue because the source of the contamination could not be identified quickly enough to keep consumers safe. FSMA 204 could have significantly reduced the amount of time it took to target the source, greatly narrowing the recall and focusing the consumer warning on a specific company or grower.

In each of these cases, traceability data rapidly identifying the source of contamination might have lessened consumers' loss of confidence in the specific commodity and hastened the pace of market recovery.

Together, these outbreaks brought into focus traceability failures that have plagued the fresh produce industry for two decades, including a reliance on handwritten records that were often incomplete. The commitment by Congress, FDA and the food industry to prevent these failures from happening again was the genesis of FSMA 204.

By contrast, the investigation of the 2011 outbreak of listeriosis associated with the consumption of fresh cantaloupe was fast and effective, due in part to the simplicity of the supply chain. FSMA 204 will bring that same efficiency to the complex, global stage.

To borrow a line from Shakespeare, what's past is prologue. What's ahead with the FSMA 204 standards will be a modern food traceability system that helps protect consumers from foodborne illnesses and helps protect the fresh produce industry from the devastating financial impact of such outbreaks.

About the Author

Robert J. Whitaker, Ph.D.,
President, Whitaker Consulting, LLC

In 2020, Dr. Bob Whitaker founded Whitaker Consulting to develop educational material and provide produce safety and technology consulting services to the fresh fruit and vegetable industries. From 2008 to early 2020, Bob served the Produce Marketing Association (now the IFPA) as its Chief Science & Technology Officer, responsible for product safety, technology, supply chain management, government affairs, and sustainability. Bob also served on the Center for Produce Safety board of directors and executive committee from its founding in 2007 until June 2020 and was the first chair of the CPS technical committee (2008-2013).

Before PMA, Bob spent 16 years in the agricultural biotechnology field with DNA Plant Technology Corporation as a researcher and finally as Vice President for Fruit and Vegetable Research and Development. After DNAP, Bob worked 10 years at NewStar Fresh Foods and its subsidiary, MissionStar Processing in produce safety, product development, and as Vice President of Process Operations. Bob's work has been widely published in several disciplines including enzymology, plant tissue culture, microbiology, food safety, and technology.

Actively involved in produce association activities throughout his career, Bob served as a volunteer leader for several national and regional industry trade groups. Bob served on the board of directors for the International Fresh Processors Association (2002-2006) becoming the chair (2005-2006) and the board and executive committee of United Fresh from 2006-2008. Bob provided technical expertise through participation on the food safety and technical committees at IFPA (chair 2000-2004), United Fresh, LGMA (2007-2009), and the Salinas Valley Grower/Shipper Association (2005-2007). Bob has been honored by several groups for technical achievement and leadership including the International Fresh-cut Processors' Association (IFPA) Technical Achievement Award (2006), USDA National Advisory Committee on Microbial Criteria for Foods committee member (2010-2012), NSF Food Safety Leadership (2015), CPS leadership (2015 and 2018), National Academies of Science Genetically Engineered Crops Review panel (2016) and the California Leafy Greens Marketing Agreement's Golden Checkmark Award for Achievement (2019).

Bob holds a doctorate in biology from the State University of New York at Binghamton, and currently consults with iFoodDS on a part-time basis.

About iFoodDS

iFoodDS is the leader in food supply chain solutions for the fresh food industry.

iFoodDS offers connected, real-time Traceability, Quality, and Food Safety solutions for suppliers, processors, distributors, grocery retailers and foodservice operators that make it easier to deliver wholesome, fresh, high-quality perishables to customers. We partner with organizations across the fresh food supply chain, enabling them to gain visibility and insight into their operations, transform inspection processes, reduce food waste, and optimize inventory quality.

In collaboration with our consulting subsidiary, New Era Partners, iFoodDS helps enterprises navigate the complexities of the FDA's Food Traceability Rule, FSMA 204. Our collective goal is to smooth the path to compliance and mitigate the impact foodborne outbreaks have on the end-to-end fresh food supply chain and its consumers.