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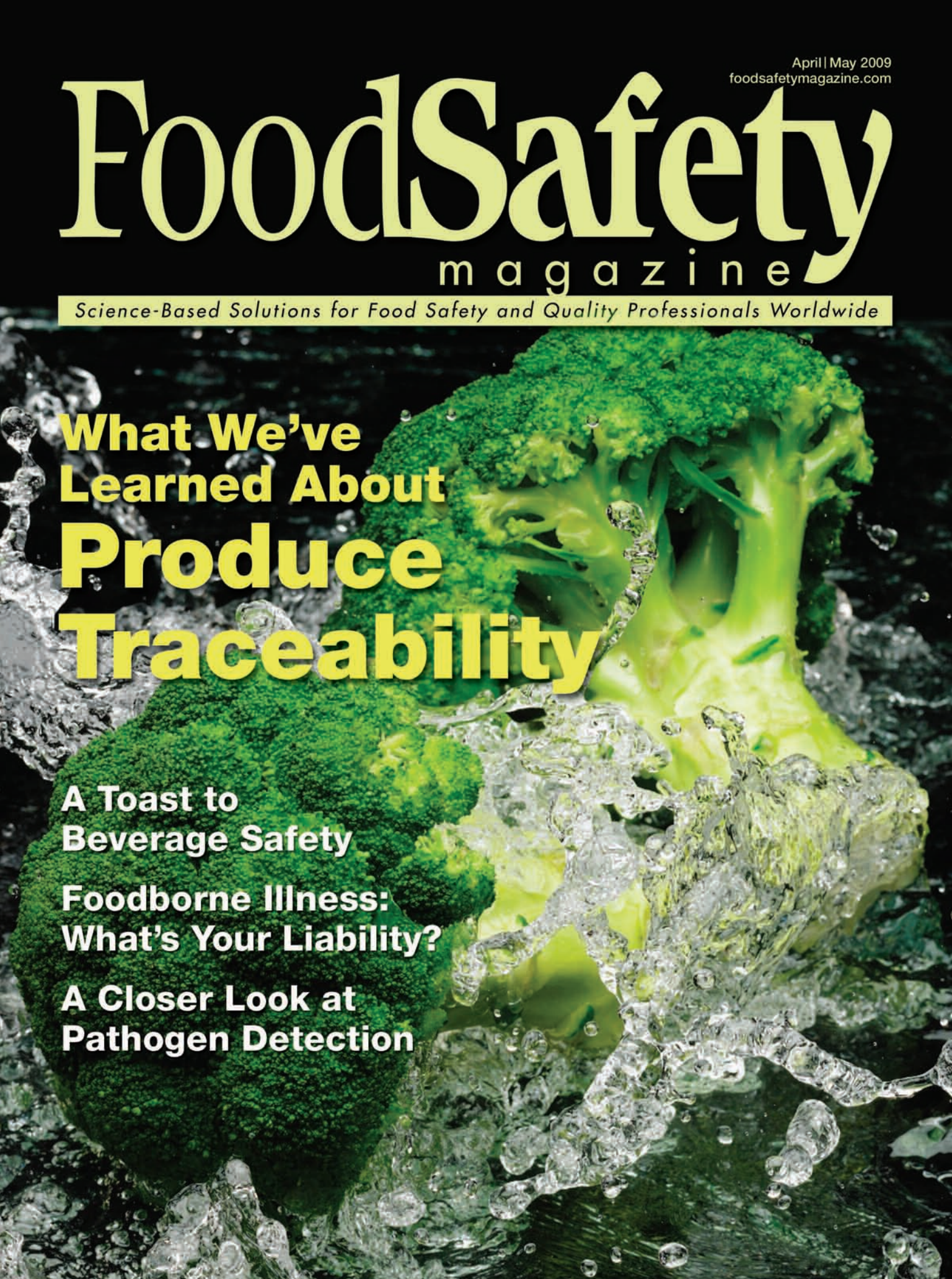

What We've Learned About Produce Traceability

A Toast to Beverage Safety

Foodborne Illness: What's Your Liability?

A Closer Look at Pathogen Detection

CONTINUOUS IMPROVEMENT TRENDS IN Produce Traceability

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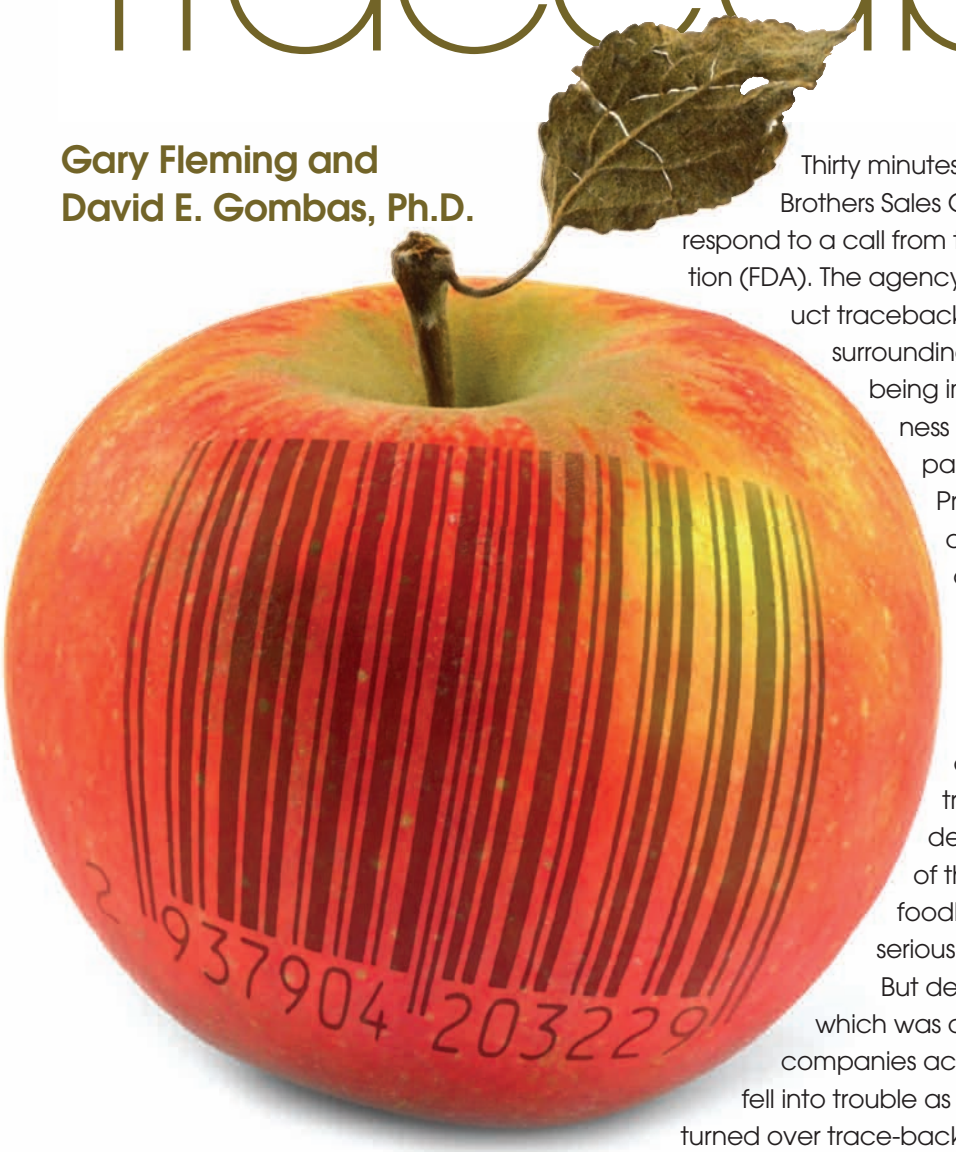

Thirty minutes is all the time officials at Procacci Brothers Sales Corporation needed in June 2008 to respond to a call from the U.S. Food and Drug Administration (FDA). The agency was seeking the company's product traceback records as part of an investigation surrounding certain types of fresh tomatoes being implicated in a serious foodborne illness outbreak involving *Salmonella* Saintpaul. Already aware of the outbreak, Procacci Brothers—a complete supply-chain produce company handling over 275 tons of fruits and vegetables per year and one of the industry's largest handlers of tomatoes—was ready and willing to comply. The company's trace-back records were at-the-ready since internal product tracking has been routine protocol for decades, and officials' understanding of the need for expediency in isolating a foodborne illness is a responsibility taken seriously.

But despite Procacci Brothers' readiness, which was duplicated by tomato supply-chain companies across the country, FDA's investigation fell into trouble as quickly as produce companies turned over trace-back records. So too would the entire tomato supply chain soon realize the speed with which a food safety incident could blow through the industry like a natural disaster.

Tracing Back Produce

The fresh produce supply chain handles an estimated six billion cases of produce in the U.S. each year and comprises a complicated sourcing and distribution system necessary to assure the quality of fresh perishable foods to consumers. Unlike other segments of the

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food industry, the entire produce marketing chain has had a longstanding legal obligation to provide an internal trail of accounting between buyers and sellers ever since the Perishable Agricultural Commodities Act (PACA) of 1930. With United Fresh Produce Association (United Fresh) at the forefront, PACA was enacted at the request of the fruit and vegetable industry to address unfair business practices unique to trading in perishable agricultural commodities. Because of the time-sensitivity inherent in the perishable commodities business, PACA protects companies dealing in fresh and frozen fruits and vegetables by enforcing a code of fair practices designed to prevent rejection of produce without probable cause, failure to promptly pay an agreed-upon price, destruction or misbranding of produce and falsification of inspection certificates. In its original interpretation, PACA is about record keeping that ensures fair business practices, but it also set the foundation for basic traceability.

The events of Sept. 11, 2001 reinforced the need to enhance the security of the U.S. and its food supply. The U.S. Bioterrorism Act of 2002 addresses this need. The act requires that every handler of food products establish and maintain records internally to document movement of its products both one step forward and one step back, from company to company, through the supply chain. The "one up, one back" concept of the Bioterrorism Act bumps PACA record keeping up a notch in the name of food safety. Compliance is easily achieved through augmenting the existing practice of record keeping authorized under PACA and through FDA's flexibility in allowing records to be kept in any format, paper or electronic, provided they contain all the required information. Today, PACA and the Bioterrorism Act records together allow product to be traced between buyers and sellers, and many companies throughout the supply chain have the ability to quickly track produce from the store all the way back to the farm.

Around the same time the Bioterrorism Act was passed in 2002, industry leaders looking to improve business efficiencies were working together on supply-chain standardization issues. To this end, an alliance was formed between the Produce Marketing Association (PMA) and the Canadian Produce Marketing Association (CPMA) to research the requirements around traceability and to create a best-practices guide for implementing traceability. Additionally, a pilot study of companies considered to have effective traceability systems was conducted to validate the guidelines outlined in the best-practices manual. Surprisingly, a key finding of the pilot was that while these companies had efficient traceability within their own walls, that system broke down when tracking products *between* companies.

True traceability is the accurate generation and recording of a product's history, including all processes that transport or transform it. This includes not only routine movements like packing, but also the mixing of lots, re-palletizing of cases and even the combining of products in food preparation. It's used not only in growing and packing but also in the distribution end, where cases can be reconfigured to form pallets. In the pilot study's discovery phase, produce industry leaders saw an opportunity to improve upon the tracking efficiencies afforded their businesses from the Bioterrorism Act's requirements by 1) standardizing trace record keeping externally across companies, and 2) moving to electronic trace record keeping. That both steps would help speed trace-backs in support of government food safety investigations was a godsend.

It's Not Easy Being Green

Then a seminal event for the produce industry occurred in late 2006: the leafy greens food safety recall. The crisis involved a large *Escherichia coli* O157:H7 outbreak associated with pre-washed spinach that affected over 200 people in more than 20 states and claimed three lives. Raw spinach and blends that contained raw spinach were recalled under suspicion of being tainted by *E. coli*. This outbreak was shortly followed by two restaurant-associated outbreaks linked to consumption of pre-washed lettuce.

In the case of spinach, once pre-washed, bagged spinach was properly identified, officials were dealing with an immediately traceable food product individually labeled with a Universal Product Code (UPC) and a lot number that revealed when the item was packed, in what facility and even whether it was packed during the morning or afternoon shift. It would be determined that the only contaminated spinach ever in the marketplace was bagged on one shift, on one day, in one processing plant, with the same lot code appearing on every bag. In the end, traceability was not problematic in the spinach investigation despite a four-week nightmare for both consumers and the industry.

"True traceability is the accurate generation and recording of a product's history, including all processes that transport or transform it."

In fact, produce industry members took note of how the standard, bar-coded UPC afforded the ability to promptly track tainted product back to its source. The case provided a shining example of how electronic coding traces product expeditiously, which stood out even more poignantly against the backdrop of an increasingly volatile food safety environment. The *E. coli* crisis lit a rocket under the produce industry's traceability efforts, which were already under way. On the heels of the outbreak, many food safety prevention efforts were established that serve produce companies today with dedicated produce safety resources. For example, California farmers came together to form the California Lettuce and Leafy Greens Marketing Agreement, which raises the bar on leafy greens safety with strong, science-based food safety protocols and state verifica-

tion. The Center for Produce Safety at the University of California, Davis was also established by PMA and others, and brings together experts from industry, government and academia to coordinate, fund and disseminate research that answers how produce can become contaminated and what can be done to stop that and ensure the safety of fresh produce worldwide.

Industry Mobilizes

Also sprouting from the aftermath of the leafy greens crisis was the Produce Traceability Initiative (PTI). Administered by United Fresh, PMA and CPMA, the initiative mobilized in late 2007 with a project steering committee that would swell within a year to more than 50 companies representing the entire produce supply chain from across the U.S. and Canada. The PTI steering committee has worked since to develop a plan for moving the industry to chain-wide electronic traceability, establishing traceability best practices and setting goals for their adoption and accountability. At the heart of the PTI effort is the recognition that true traceability–as well as the efficiencies, accountability and security that go with it–requires a common language of information, chain wide and eventually worldwide.

The plan adopts a standardized system of case barcoding for all produce sold in the U.S. that allows for 1) streamlined marking and consistent identification of each case of produce; 2) scanning and collection of case data by all buyers, receivers and handlers; and 3) electronic storage of such information that can be tracked throughout the distribution chain. The plan builds upon the effectiveness of the industry's current traceability procedures as required by PACA and the Bioterrorism Act–companies don't need to scrap their current tracking systems, just augment them–and improves internal efficiencies. This standardized system would also significantly improve the ability of industry and federal officials to narrow the impact of foodborne illness outbreaks and recalls, protecting both consumers and industry members.

> "The U.S. Bioterrorism Act of 2002…requires that every handler of food products establish and maintain records internally to document movement of its products…through the supply chain."

The PTI is a huge but necessary undertaking for the produce industry, which is why its steering committee worked carefully for months to draft a proposed plan that members vetted with their operations experts, and then reassembled to amend the draft based on feedback received and vetted it again. That process repeated itself until the steering committee arrived at a real-world solution that members felt could be reasonably implemented by all produce companies–large and small–across the entire supply chain, including all companies operating within the U.S. market and those exporting to the U.S. While the PTI certainly provides benefits to the industry, the plan clearly supports vital public health goals as well.

After 10 months of work, in October 2008 the PTI steering committee announced its vision in a seven-step action plan designed to achieve chain-wide electronic traceability no later than 2012. The steering committee endorsed an industry-wide commitment to case identification based on GS1 standards for the effective management and control of supply chains. GS1 is a global standards organization with affiliates representing 145 countries worldwide in over 25 different industries, with a membership in excess of two million. The GS1 system provides standard protocols that help uniquely identify trade items (products and services), logistic units, locations, assets and service relations worldwide. The PTI steering committee recommended that the produce industry universally adopt the use of the GS1 Global Trade Item Number (GTIN). This number is analogous to the UPC used at the item level; what the UPC does for item-level identification, the GTIN does for case-level identification. Both numbering protocols are managed by GS1. The systematic use of GTINs at the case level will enhance total produce supply-chain traceability by allowing direct, standardized interaction between differing internal coding systems that are unique to each company.

In addition to the use of a GTIN to identify the "manufacturer" of the product and the produce that is in that specific case, PTI's standardized approach uses one other piece of information: the lot number. These two pieces of information will be on each case and readable by the human eye. The origin of the product and the lot number assigned to it–information that the industry already tracks internally–will now be immediately identifiable by any handler at any produce company reading that case's label.

What's more, the information will also appear on that label in a barcode that each member of the supply chain will scan. Having the GTIN and the specific lot number will enable each handler to have a record of when that particular case entered and left its facility. Think of these pieces of information as a baton that is passed by one runner in a relay race to the next; that common information then travels–and can be tracked–from the start to the finish lines. This information will now be available in a database at each company's location, accessible at a moment's notice, even when the physical case has left its facility or has been discarded.

As the Bioterrorism Act requires companies to track one step up and one step back in the supply chain, no single company is responsible for tracking the product from harvest all the way to the store. This is the job of the FDA. As such, FDA needs the ability to track product from the source all the way to the store. The PTI's vision gives FDA the

ability to do this, while allowing each company to maintain its own internal traceability processes. It simply requires companies to augment their systems to include both the GTIN and the lot number, which most already record, and to electronically store this data in their internal systems.

The PTI action plan outlines seven key elements and milestones for implementing the whole-chain traceability process. The associations also commit to providing information and educational resources to help industry members achieve the plan's milestones by 2012.

1. Complete by Q1 2009 – Brand owners must obtain a GS1-issued company prefix.
2. Complete by Q1 2009 – Brand owners must assign 14-digit GTINs to all case configurations. The steering committee highly recommends that companies use the number assignment strategy already created by the trade associations to minimize the number of GTINs created and to allow for consistency across industry segments.
3. Complete by Q3 2009 – Brand owners must provide and maintain their GTIN information (and corresponding data) to their buyers.
4. Complete by Q3 2010 – Those parties packing the product are responsible for providing the GTIN and lot number in a human-readable form on each case.
5. Complete by Q3 2010 – Those parties packing the product are responsible for encoding the GTIN and lot number in a GS1 128 barcode.
6. Complete in 2011 – Each handler of the case must read and store the GTIN and lot number for every *inbound* case they receive.
7. Complete in 2012 – Each handler of the case must read and store the GTIN and lot number for every *outbound* case they ship.

"The (Produce Traceability Initiative) (PTI) action plan . . . outlines seven key elements and milestones for implementing the whole-chain traceability process."

Another Foodborne Illness Outbreak

A year and a half after the spinach outbreak–and while the PTI steering committee was elbow-deep in its work devising the aforementioned chain-wide traceability plan–another foodborne illness outbreak made the news in May 2008, this time involving *Salmonella* Saintpaul. Based on the Centers for Disease Control and Prevention's (CDC's) in-house epidemiological investigation, FDA implicated certain types of tomatoes. Eventually more than 1,400 people across the United States and Canada would be sickened as the outbreak's investigation dragged on for months before the source–raw jalapeño peppers–was properly identified.

As the investigation spiraled, speculation surfaced regarding industry's apparent inability to trace back produce as being behind the ineffective investigation. In reality, FDA's use of the industry's trace-back information effectively traced tomatoes eaten by sick consumers back to the farm. The problem was that those trace-backs kept pointing to different farms, and failed to identify a common point where all of those tomatoes could have been contaminated, whether at the farm or in repacking at the wholesale level. In essence, trace-back worked; it just wasn't confirming the tomato hypothesis that the CDC had advanced from its initial epidemiological investigation.

Having said that, the industry's traceability system was not entirely without problems. Because chain-wide electronic traceability has yet to exist, the FDA, in attempt to follow a product through the supply chain from company to company, had to translate each produce company's proprietary tracking system and try to make it correspond to other companies' proprietary tracking systems. Given that the Bioterrorism Act does not mandate electronic record keeping and that FDA consequently is not equipped to process trace-back records electronically, all trace-back records were requested and submitted on paper. Horror stories exist of field staff faxing hundreds of pages of printed electronic records to FDA headquarters for someone to try to read through and connect the dots between multiple traceability systems of multiple produce companies throughout the supply chain to make sure that all the details–such as number of boxes, brand names, lot codes and ship/receive dates–correlated exactly on invoices, bills of lading and other such documentation.

While the grocery industry has had electronic traceability for many years, for a number of reasons, that has been more difficult to achieve in the more diverse world of fresh foods such as produce. However, the reality of today's food safety environment demands that the produce industry move from paper traceability systems to electronic systems. In order for traceability to work effectively as an outbreak management tool, it remains imperative that a tracking system possess the ability to quickly and accurately identify the product, locate the source, determine the amount of implicated product and which shipments contained the implicated product and then notify those who received the implicated product–all within hours.

Still, while technology provides a means toward that end, it is only a facilitator, not an end in itself. Both flawed epidemiological marching orders at the onset–an approach that relies on the inexact science of consumer recollection, local health officials' speculation and federal protocol–and a bottlenecked paper trail proved not to be conducive to protecting public health.

Investigating the Investigation

Nonetheless, in the summer of 2008 as the investigation into *S.* Saintpaul lengthened, rumblings cropped up in Congress and the agencies that the federal government should step in to man-

date produce traceability. The House Committee on Agriculture and the Horticulture and Organic Agriculture Subcommittee scheduled hearings on the matter, and the FDA subsequently planned a series of public meetings for that fall.

In late July, when the produce industry's PTI steering committee was compiling its conclusions for presentation in the final action plan slated for announcement that October, the federal government began public hearings on produce tracking systems. Leaders of the PTI's founding associations and tomato industry executives testified in front of congressional committees in an attempt to assure the nation of the industry's traceback capability and to urge the government to allow industry to complete its PTI work to enhance its manual paper capability and achieve electronic, chain-wide traceability.

"Industry cannot reflexively oppose regulation," stated PMA President Bryan Silbermann in his testimony before the two committees, "but governmental action must recognize and harness the ingenuity of the private sector to improve food safety and to gain back the full confidence of our consumers. At the same time, it is not the private sector's role to wait passively for government to regulate; we must act."

Among produce industry members, it is widely believed that government should support the industry PTI rather than create its own standards and regulations–and this is not a self-serving motive. The fresh produce supply chain comprises a complex web of growers, shippers, packers, repackers, distributors and other providers. The men and women of the produce industry possess an intimate knowledge of unique details related to growing seasons, regions and produce varieties that correlate with distribution areas and provide unmatched expertise critical to isolating the tainted product's source and resolving a recall as quickly as possible.

"The produce industry understands better than anyone that we need the most efficient and quickest traceability systems possible," testified United Fresh President and CEO Tom Stenzel. "We have the most to gain from isolating produce that may be part of a problem, as quickly as possible. The fewer people who get sick, and the quicker a problem is contained, the better off we are. This industry would storm the barricades to quickly identify the real source of contaminated food, no matter where that finger points.

"And that brings me to the other incentive we have to continuously enhance traceability–we have the most to gain by ruling out concerns about produce that is clearly not related to a problem. Our goal in every case of a foodborne disease outbreak must be to find the specific source as quickly as possible and free the rest of the industry from suspicion."

> "The issue of how to improve produce traceability is not just about technology, it's about changing business practices…"

It was that veil of suspicion during the *S.* Saintpaul crisis that for months brought the tomato supply chain to its knees, as retail and foodservice customers rejected all deliveries of tomatoes and put a hold on new purchase orders, as full warehouses of perfectly healthy tomatoes and tomato products were hauled to the dump, as fruit rotted on the vine, as fields were plowed under and as new plantings were canceled. The tomato supply chain has lost untold millions to safeguard public health, and tomato sales suffer to this day as a result of weakened consumer confidence in the product.

You Say Tomato, We Say Untold Millions Lost

Dr. David Acheson, associate commissioner for foods at FDA, also testified before the committees, announcing that just days earlier, the agency had found the exact strain of *S.* Saintpaul in peppers and water sources in Mexico. Nonetheless, the agency refused to clear tomatoes. And so to some industry members who track produce efficiently every day and whose intimate knowledge of the sourcing and distribution of perishable commodities quickly rendered the implication of tomatoes nonsensical, claims of the investigation dragging on because of FDA investigators having to pore over reams of paper records and deal with mysterious spider webs in the supply chain simply did not ring true.

"We believe the CDC and the FDA incorrectly presumed tomatoes to be associated with the *Salmonella* outbreak," Florida Tomato Exchange Executive Vice President Reggie Brown told the congressional committees.

"The Florida tomato industry has suffered tremendously. Everyone associated with Florida's tomato industry, all the workers, farmers and packers in the designated areas and outside those areas have been harmed."

A few months later, at the FDA's scheduled public meeting on the issue in October–the same time industry's PTI final action plan was released–produce executives repeated their urging to the government to first look at the industry's model before considering further steps.

Produce leaders underscored that the PTI plan, developed by a supply chain-wide steering committee, provided a realistic and achievable approach that directly addressed FDA's desire to enhance product tracing systems for fresh produce and improve the agency's ability to use this information to identify sources of contamination associated with future fresh produce-related outbreaks of foodborne illness.

Attempting to Rebound

With the *S.* Saintpaul outbreak resolved and faded from the headlines, injury to the tomato industry remains an open wound. Even today, officials at Procacci Brothers can still be found dealing with the wreckage of 2008. The *S.* Saintpaul crisis, cou-

pled with exorbitant fuel costs and a tanking economy, brewed a perfect storm of disastrous proportions.

Having lost tens of millions of dollars, Procacci Brothers recognizes its greater fortune of not going out of business, as have many tomato companies that were unable to recover from the crisis. Procacci officials proudly share that they are reinventing and reselling themselves, including working toward compliance with the PTI's action plan. The issue of how to improve produce traceability is not just about technology, it's about changing business practices–both industry practices and federal government practices regarding foodborne illness investigations. Because no system is risk free, there most likely will be a next time for a perishable commodities safety crisis. In the absence of better preparedness, both the consumer's and the produce industry's sense of security is undermined by inadequacies that are unacceptable in today's food safety environment.

As summed up by one Procacci Brothers official, "One tainted tomato anywhere is one tainted tomato everywhere." ■

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