The Use of Critical Tracking Events and Key Data Elements to Improve the Traceability of Food throughout the Supply Chain to Reduce the Burden of Foodborne Illnesses.

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Dedication

This dissertation is dedicated to my late father, David Miller. I know he would have been proud.

Abstract

From 2005 to 2010 many large nationwide foodborne illness outbreaks were associated with commercially distributed food. In some of these outbreaks the source was not immediately identifiable because product distribution information was incomplete or difficult to collect or interpret and the outbreak vehicle could not be traced to its source. The primary objective of this research is to characterize and propose how data could be more systematically defined and collected throughout the food supply chain to more rapidly determine the source of foodborne illness outbreaks.

This research proposes a conceptual framework for addressing the food traceability challenge. While specific technical solutions exist, none are capable of satisfying all needs of the various food supply chains. What has been missing is a common conceptual framework within which a variety of solutions can co-exist. Any such framework must preserve flexibility, scalability and adaptability. Individual technical solutions must be capable of satisfying requirements of the food industry while simplifying and improving aggregation and interpretation of key data for both industry and regulators faced with outbreak investigations.

To understand the development of the conceptual framework, traceback methods by state regulatory agencies were used to complement traditional epidemiological cluster investigation methods and confirmed hazelnuts as the

vehicle in a multi-state outbreak of *E. coli* O157:H7 infections. This outbreak investigation demonstrates the use of product traceback data to rapidly test an epidemiological hypothesis.

This conceptual framework was validated during an outbreak of 6 cases of *Salmonella* Newport infection, which identified fresh blueberries as the cause. Initially, traditional traceback methods involving the review of invoices and bills-of-lading were used to attempt to identify the source of the outbreak. When these methods failed, novel traceback methods were used. This investigation demonstrates the emerging concepts of Critical Tracking Events (CTEs) and Key Data Elements (KDE) related for food product tracing. The use of these shopper-cased data and the event data that were queried by investigators demonstrates the potential utility of consciously designed CTEs and KDEs at critical points in the supply chain to better facilitate product tracing.

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Chapter 1. Introduction and Literature Review

Introduction

Traceability is “a record keeping system designed to track the flow of product or product attributes through the production process or supply chain” (1). Traceability, in order to protect public health, should encompass all aspects of the food system, starting at the point of harvest and continuing to retailers. Animal feed, as well as food packaging, should also be included in a robust food chain traceability system.

Over the past decade there have been a number of large nationwide outbreaks involving commercially distributed foods that have resulted in hundreds or thousands of cases of confirmed illness (2–8). In many of these outbreaks, traditional epidemiological methods have not quickly identified a statically associated food exposure and traceback investigations have been needed to help characterize the probable food vehicle. These traceback investigations could be completed more rapidly and with a greater degree of accuracy if the current data requirements for food traceability were better defined and aligned across the food supply chain and if regulatory agencies were able to share this information more quickly and accurately between local, state, and federal officials. For businesses, large foodborne outbreaks have very measurable costs in terms of lost sales, lost confidence, and increased morbidity and mortality (9–12).

The primary objective of this research is to characterize and propose how data could be more systematically defined and collected throughout the food supply chain to more rapidly determine the source of foodborne illness outbreaks.

The specific aims of this research are to:

1. Propose a systematic approach to analyzing processes throughout the food supply chain so that critical processes and key data elements related to food production and distribution can be collected in a consistent manner to better facilitate food traceability.
2. Illustrate the complexity of a multistate regulatory investigation using current data sources in the food supply chain that have not been optimized for traceability.
3. Demonstrate the potential utility of using non-traditional data sources (shopper card information and point-of-sale database information) to traceback an outbreak of *Salmonella* associated with blueberries.

Literature Review

Traceback investigations

Traceback investigations are used as an extension of an epidemiologic foodborne illness investigation to determine the source of an outbreak. Numerous foodborne outbreaks over the past several years have demonstrated the importance and the need for rapid traceability of food products sold to

consumers (3,6,7,13–17). The Food Safety Modernization Act required the Food and Drug Administration (FDA) to determine how technology could be used by the food industry and the FDA to improve traceability in the food supply chain (18).

Traceforward investigations

Traceforward, sometime called “tracking”, is the capability to find a product based on specific criteria while it is handled along each point of the supply chain. This type of traceability is typically used by industry when recalling contaminated food products and can be challenging when recalling products manufactured with a contaminated ingredient (7).

External Traceability

External traceability represents transactions between companies in the food supply chain that capture data and information about specific product movement between companies (19).

The food industry is required to maintain external traceability through existing business records under the Bioterrorism Act of 2002 and this information is generally available in most traceback investigations (20).

Internal Traceability

Internal traceability represents product transformations or movements that occur within a single company of processing facility in order to identify all inputs used to manufacture a finished product. Internal traceability is generally more difficult to implement for the food industry because it requires additional processes and

data capture points in order to track incoming ingredients and link them to discrete finished products. If internal traceability is not practiced, this can result in the loss of supply chain traceability for that location in a traceback investigation.

Outbreaks Involving Traceback Investigations

Foodborne illness outbreaks where traceback investigations have been conducted typically involve a common set of criteria (21):

1. There is a PFGE subtype cluster of cases that likely represents a common source outbreak; and
2. Cases occur in multiple locations or jurisdictions (particularly if they occur in multiple states); and
3. Interviews of case-patients reveal no obvious common exposure that can explain the outbreak, suggesting that the outbreak vehicle is a commercially distributed food item; and
4. A vehicle cannot be clearly implicated with traditional epidemiologic, laboratory, and environmental investigation methods alone.

A few examples of such outbreaks where a traceback investigation played a significant role in determining the source of the outbreak include a 1990 and 1993 outbreaks of *S*. Javiana and *S.* Montevideo associated with tomatoes from the Southeastern United States (13); a 2006 nationwide outbreak of *E.coli*

O157:H7 associated with spinach (2); a 2006 *E.coli* O157:H7 outbreak associated with iceberg lettuce consumed in fast-food chains (15); a nationwide *S.* Saintpaul outbreak in 2008 originally associated with tomatoes and later linked to jalapeno and Serrano peppers (3); a nationwide *S.* Typhimurium in 2009 associated with peanut butter and other peanut containing products traced to two manufacturing facilities in Georgia and Texas (6,7); a 2007 cyclosporiasis outbreak in Canada associated with basil (14); an *E.coli* O157:H7 outbreak in 2011 associated with hazelnuts (16); a *S.* Newport outbreak in 2010 associated with blueberries (17); and a *S.* Braenderup outbreak in the Southern United States associated with mangoes (22).

Current Regulation in United States

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Bioterrorism attacks using anthrax and mailed letters in 2001 prompted Congress to pass the “Bioterrorism Act” of 2002 (20). Section 306 of the Act outlines and details the current record keeping requirements for food manufacturers, processors, transporters, distributors, brokers, and importers that form the basis of the current “one-forward, one-backward’ traceability system in the United States. Farms and restaurants were exempted from the record-keeping requirement. The language of this Act specifies external traceability requirements but did not clarify traceability within a firm or facility. This lack of internal traceability has lengthened the time required to accurately identify the

source of some large national outbreaks, most notably the *Salmonella* Saintpaul outbreak of 2008 that was initially thought to be associated with tomatoes (3).

Food Safety Modernization Act of 2011

In response to the large number of nationwide outbreaks in the 2000s, the Food Safety Modernization Act was signed into law in January 2011. Section 204 of the Act, requires the FDA to establish a product tracing system based on the results of several pilot projects examining traceability for high risk produce and manufactured food products. The food industry will be required to maintain more complete records for high-risk foods based on the record keeping requirements promulgated by the FDA. This legislation has taken longer to implement that specified in the Act itself and the record keeping requirements required for industry remains unclear (23).

Current Frameworks and Standards

In addition to legislation, a number of countries and organizations have developed framework guidance documents and some have also established a minimum set of voluntary data standards needed for supply chain traceability (24). Many of these international standards encourage the use of the GS1 standards which are maintained by the international non-profit organization, GS1 (19).

Technologies and Data Structures for Food Traceability

Traceability Standards

International non-profit standard organizations have proposed data standards allowing supply chain partners to share product information consistently between and within food companies throughout the supply chain. These standards specify data formats that are independent of a transfer technology or medium (19).

Regulatory requirements for the adoption of a single data standard in the food supply chain do not currently exist in the United States (18).

Summary

The average supermarket in the United States in 2010 carried over 38,000 items (25). While not all these items were food products, the increased availability of more food products to consumers has increased the complexity of the food supply chain and makes tracing a food back to its source more difficult. Between 1987 and 1997 the number of individual produce items in grocery stores increased 94 percent (26). A number of large nationwide outbreaks have demonstrated the need for and the usefulness of improved food traceability (2,6–8,27).

Systematic improvements in food traceability are required to shorten the time required by investigators to trace a suspect food back to its source (18).

Improvements in investigatory coordination will also improve response time and may prevent additional illnesses in future outbreaks (16,21).

Chapter 2. The Critical Tracking Events (CTE) Approach to Food Traceability

The Critical Tracking Events (CTE) Approach to Food Traceability

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Introduction

The concept of food traceability can be simplified by defining the problem in terms of the timing of specific data needs of public health officials and regulators during outbreak and traceback investigations. This shows how the problem may be broken into phases where initial phases may proceed rapidly in order to bring investigators quickly to points of interest within the supply chain. These time and cost saving measures permit thorough investigations where needed with minimal changes to operations by supply chain participants. This leads directly to the conceptual model, similar to the Hazard Analysis Critical Control Point (HACCP) model, which would be used by industry to identify “Critical Tracking Events” (CTEs) in their own operations throughout the supply chain. The powerful concept of CTE is gaining wide acceptance by the food industry and has already been used to solve previous foodborne outbreaks (15,17).

Finally, this paper proposes methods for fostering technical innovations through research and testing by combining stochastic modeling and pilot projects in harvesting, processing, distribution and retail food facilities.

Foodborne outbreaks represent a significant burden of illness in the United States and internationally causing significant morbidity and mortality (28,29). While the majority of these illnesses are of an unknown etiology, a significant

number are associated with commercially distributed foods. As the complexity and speed of the food supply increases, private industry, government regulators and public health officials have been challenged in tracing potentially implicated foods during and after foodborne illness outbreaks. Notable examples include outbreaks associated with spinach, peanut better, shell eggs, fresh produce, and pet food (2,6,7,30,31).

As a result of these outbreaks, improved recordkeeping and traceability requirements were included in the landmark passage of the Food Safety Modernization Act (FSMA) in January of 2011. This Act specifically required the Food and Drug Administration to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak.

The primary goal of food traceability is *not* food safety. The primary goal of food traceability for public health investigators and regulators is to improve investigational efficiency, but in order to do so the food industry must make investments in their processes and production systems that allows needed information to be collected. Specifically, the goal of improving food traceability is to improve the *speed* of investigations as well as the *accuracy* of results. Therefore, the problem of food traceability requires a mindset that is first rooted in logistics rather than food safety. Of course, achieving improvements in food

traceability will likely result in fewer cases of foodborne illness, reductions in the amounts of food discarded, as well as added protection of industry segments and/or product brands from erroneous implication in outbreaks. Also, increasing the number of successful outbreak investigations will lead to more opportunities to learn from mistakes through environmental assessments, resulting in accelerated improvements to food safety throughout the supply chain. Therefore, increased food safety is a likely, but secondary benefit of improvements in logistical performance related to food traceability. Successfully improving traceability throughout the supply chain relies on the food industry realizing the primary benefits of improving logistical performance (by increasing efficiency and lowering operating costs) while concurrently complying with improved traceability requirements to satisfy the public health and regulatory communities.

While the link between food traceability and food safety exists, there are a few layers of activity, action and investment required to better secure that linkage. Historically, the food industry and Food and Drug Administration have tended to view food traceability exclusively through the lens of food safety rather than logistics and that may have slowed innovation and adoption of effective food traceability solutions. Food safety tends to involve conditions of handling, processing and production as opposed to movement of products through the supply chain. Specifically, food safety is a quality function whereas food traceability is a logistical one. While safety is always a concern with food,

logistics involves a different perspective, different skill sets and different tools than production oriented quality control and assurance.

Currently accepted concepts for food traceability

Based on current regulatory requirements to maintain one-forward-one-back (OFOB) traceability documentation (20), most supply chain participants are comfortable with the concepts of 'internal' and 'external' traceability. However, traceability requires that linkages through each operation are maintained, so these definitions of 'internal' and 'external' are not particularly useful in trying to comprehend the problem and possible solutions. Some operators argue that this definition is necessary to protect internal proprietary information, but a well-designed traceability system alleviates these concerns. By focusing on solving 'external' traceability at the expense of 'internal' traceability, effective traceability solutions remain elusive. Therefore, eliminating the notions of 'external' and 'internal' traceability in favor of the more comprehensive concept of Critical Tracking Events (CTEs) that are applicable throughout the supply chain should offer greater efficiency as well as data security.

The old concept of 'external traceability'

Transactions between growers, processors, distributors, shippers, brokers and brand owners (Figure 2.1) represent *external traceability* and all segments of the supply chain must participate for such a traceability system to be effective. Missing data slows or stymies investigations. External traceability is largely in practice today throughout the supply chain since companies currently maintain

records of shipments received from suppliers and shipped to customers for the regular business practices of invoicing and payment.

The old concept of 'internal traceability'

Internal traceability (Figure2.2) requires that food processors or distributors track internal inputs that change the identity or configuration of the product they are selling. For food manufacturing, internal traceability may require that all lot code or batch information for the ingredients (grain, corn syrup, flavorings, vitamins, etc.) that are used be recorded and stored. For a distributor, internal traceability may require that multiple data elements be recorded if cases of product from varying lots are used to create a pallet (or an equivalent logistical unit).

What is sometimes referred to as 'internal traceability' is not actually traceability, but rather a good manufacturing practice. There is no doubt that these data are useful to outbreak investigations, but they are not needed in any investigation until they are actually required by investigators due to implication of the specific operator in a specific outbreak. In other words, investigators should only need these data from operators implicated as a likely source of contamination. Forcing investigators to dig into these records of each supply chain operator, whether implicated or not, wastes precious time of both investigators and operators, which may jeopardize the entire investigation. Relying on these data for routine traceability is unwieldy and unnecessary. Better approaches are needed to more quickly identify the most likely sources of contamination in order to avoid wasting

precious time and money of operators who should be excluded from an investigation.

Figure 2.1. Example of external traceability. A food manufacturer produces a product and tracks the distribution of that product to a distribution and retail location.

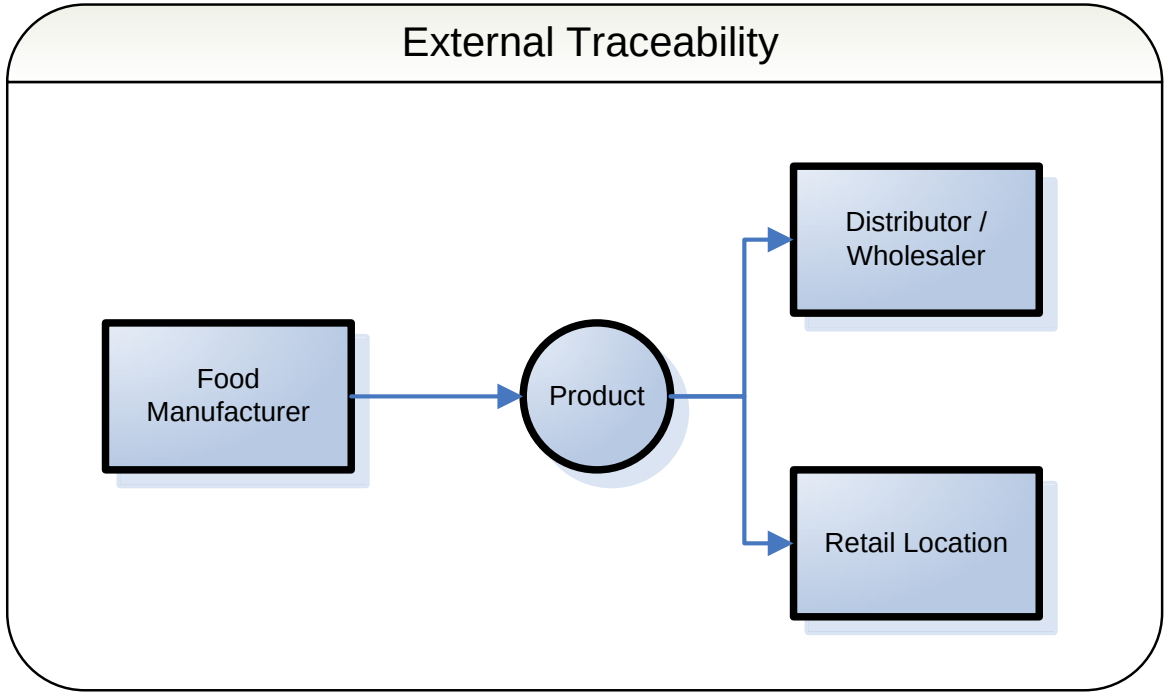
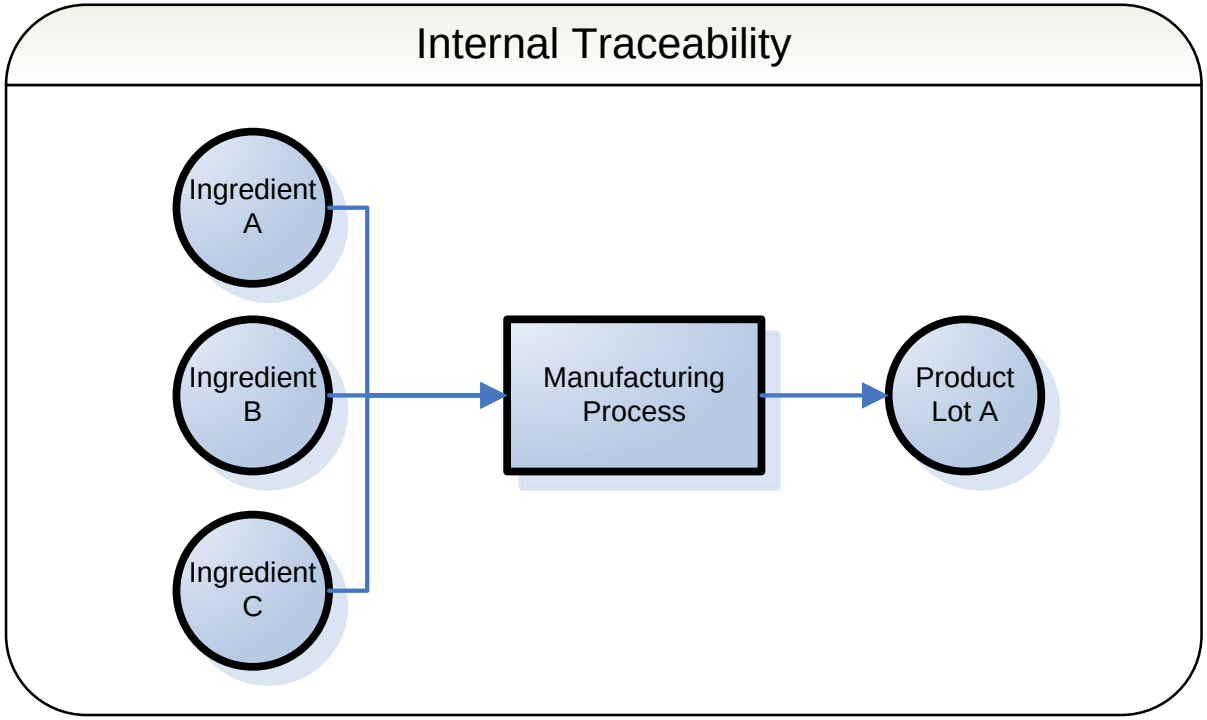

External Traceability
Food Manufacturer
Product
Distributor / Wholesaler
Retail Location

Figure 2.2. Example of internal traceability. A food manufacturer produces a prodcut from three ingredients. These inputs are recorded and related to Lot A of the finished product.


Internal Traceability
Ingredient A
Ingredient B
Ingredient C
Manufacturing Process
Product Lot A

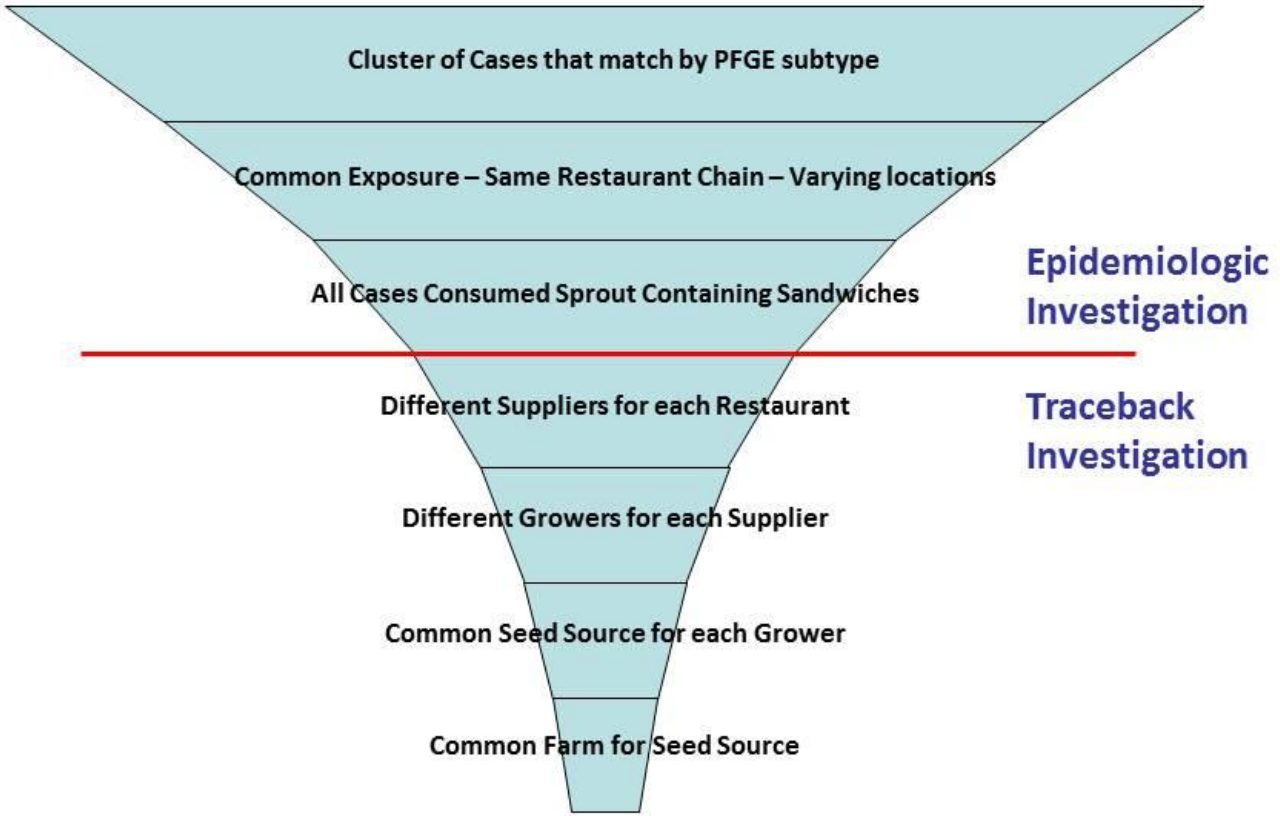
An Example Investigation

Traceability should cover the entire food supply chain; from animal feed to finished food products regardless of risk classification. Numerous foodborne outbreaks over the past several years have demonstrated the importance and need for rapid traceability of food products sold to consumers. More rapid traceability can aid and clarify foodborne illness investigations by aligning product distribution data with epidemiological exposure data. These investigations could be completed more rapidly and with a greater degree of accuracy if current data requirements and collection practices for food traceability were better defined and aligned across the food supply chain.

Figure 2.3 shows a cluster of illnesses matching a Pulse Field Gel Electrophoresis subtype identified by epidemiologists at a state health department. Due to the difficulty and cost of traceback investigations, significant clusters of illness must be identified prior to an investigation commencing. Once the cluster has been identified, epidemiologists interview specific cases and try to determine commonality such as dining at operations of the same restaurant chain. Further investigation finds that all cases consumed some type of sprout containing sandwich at each restaurant location but the source of the sprouts remains unclear.

Figure 2.3. Conceptual diagram of a traceback that supports an epidemiologic investigation.

Conducting a Traceback Investigation



While the epidemiological investigation may identify a plausible source, the regulatory investigator must trace the likely exposure to a point of convergence or commonality in the supply chain in order to identify the “source” of the outbreak.

Continuing with the example, once an outbreak vehicle is identified, the epidemiological investigation ends with the possible recommendation that persons not consume sprout-containing sandwiches at these locations. The traceback investigation is an extension of the epidemiological investigation and it serves two purposes:

1. It supports the epidemiological associations by confirming that temporal and physical distribution of suspect products could adequately match the case exposures, and;

2. It further characterizes the source of the outbreak, thereby increasing the likelihood of a meaningful intervention to protect public health.

In Figure 2.3, this concept is demonstrated when the investigation moves from the information generated in the epidemiological interviews to the information collected by a food-regulatory agency based on record collection and in-field investigations. An investigation of the invoices and bills-of-lading from each restaurant location where a case of illness was reported shows that each

restaurant received their sprouts from a different supplier. Further investigation of the records from the suppliers shows that they received their sprouts from a number of different growers. A review of the grow-logs, seed sources, and invoices at each of the sprout grower locations shows that all of the seed in implicated time frame would have come from a single seed supply company. A review of the lot-codes for the implicated seeds shows a common lot-code of seed was used at each grower in the implicated time frame and further investigation shows that the lot-code corresponds to a single farm that produced all of the questionable seed.

It isn't until all of these data are collected and analyzed that a truly meaningful public health intervention, in the form of seed and sprout recalls and a market withdrawal of the implicated lot-code, can be made. As might be imagined, such an investigation is complicated and time and resource intensive. Often, outbreaks subside before investigators are able to pinpoint a cause resulting in wasted time and effort of both doing the investigating and those being investigated.

Traceforward investigations

Traceforward, sometime called "tracking", is the capability to find a product based on specific criteria while it is handled along each point of the supply chain. This is a critical feature of any traceability system because companies must be able to identify and locate their products within the supply chain in order to withdraw or

recall them whenever necessary. Once a food item or ingredient has been associated with illness, improving forward traceability through the channels of distribution can prevent further consumer exposure and prevent additional cases of illness. Additionally, labeling on consumer packaging for manufactured foods with information containing lot or batch codes will allow consumers to easily identify products in their homes that may be associated with a recall or outbreak.

Limitations of current systems, technology and thinking

Improving investigatory efficiency requires knowledge of the process of investigation; supply chain logistics, food handling and production as well as associated technological developments in these areas. However, recent efforts have focused on testing existing food traceability practices and/or augmenting these practices with not-well-understood emerging technologies such as radio frequency identification (RFID) in the hope that they might offer a 'silver-bullet' style solution (32,33). Efforts have also been made to coordinate use of specific data elements throughout the supply chain, but with limited success (e.g. Produce Traceability Initiative or "PTI"), because there simply can never be a one-size-fits-all solution for such a large, complex and dynamic web of supply chains (34). What is needed is a more general framework that can be applied to a variety of situations. This paper proposes that this framework is offered by the concept of "Critical Tracking Events."

One-forward-one-back

Currently, food traceability revolves around the concept of “one-forward and on-back” (OFOB), which is often also referred to as “one-up and one-down” (OUOD). This approach is popular because it doesn’t require operators to do anything other than to maintain customary business records that most operators already maintain without the additional consideration of food traceability. The concept of OFOB requires that each operator be able to determine, within a reasonable amount of time, and typically within 24 hours, the identities and locations of immediate suppliers and customers. Production records, purchase orders, sales orders and invoices as well as shipping and receiving records substantially satisfy the basic food traceability requirements of OFOB. From the perspective of the operator, OFOB “works” and requires little if any additional investment other than what might normally enhance business productivity in terms of improving efficiency of data storage and retrieval. Without even considering traceability, responsible operators already maintain a variety of important business process records such as payroll, production, receiving, shipping, sales orders, invoices, purchase orders, inventory and quality control data. As mentioned, most of these data are only useful to food outbreak investigators after likely sources of contamination have been identified.

Indeed, OFOB does work, but the problem is that it is slow, inefficient and often ineffective for investigators, resulting in too many unsolved outbreaks, implication of incorrect products, unnecessary damage to industries and brands.

A better understanding of the investigative and recall processes helps to demonstrate why OFOB is likely to be incapable of substantially improving food traceability accuracy and speed regardless of capital investments made. The information contained in business process records simply cannot be collated and analyzed quickly enough by investigators to quickly reconstruct the supply chain and identify points of convergence.

The investigative and recall process generally begins with epidemiological evidence of an outbreak. As illnesses are being reported, epidemiologists must wait to identify genetically related “clusters” of multiple reported illnesses before initiating an investigation. Once one or more clusters are deemed to be sufficiently promising to pursue, investigators attempt to discover the most likely foods and/or ingredient suspects and their most immediate source (e.g. package, store, restaurant, etc.). Typically, multiple foods and/or ingredients are suspect and multiple simultaneous traceback investigations must be initiated.

For each suspect, investigators seek to learn the immediate source of the suspect product (i.e. one back). Requests for information are made from suppliers in order to identify subsequent suppliers. In this manner, investigators follow the trail backwards until the source of the outbreak is identified by multiple

traces converging upon a particular item and/or location or the trail simply “goes cold” (16).

Points of convergence provide investigators with the greatest degree of confidence in identifying potential sources of outbreaks. Once one or more points of convergence are identified, and environmental assessment consisting of onsite inspections, sampling and testing may or may not confirm the cause and a decision must be made whether or not to recall suspected product as well as define the scope of the recall. Then the OFOB process works in reverse in order to identify and remove implicated product from the supply chain; typically referred to as a product recall.

The problem with OFOB is that it is slow and inefficient. OFOB is slow because investigators must work their way backwards one supply chain node at a time and each node may use the customary 24 hours to provide data that identifies the next node in the chain. It is inefficient because investigators must simultaneously pursue suspect foods and ingredients that are not a cause of the problem and this not only wastes time for investigators, but it also wastes time of all operators who receive requests for such data. As time is spent, people may continue to consume contaminated food, the number of illnesses increase and the likelihood of confirming the correct source of the outbreak diminishes.

Anything done to improve food traceability performance, particularly with respect to government regulation, should have the potential to significantly reduce the time required to identify points of convergence in the supply chain. Approaches that fail to improve food traceability performance may add substantial costs to operators, which are likely to be passed on to consumers in the form of higher food prices. Poorly designed or implemented regulations also raise the barrier to entry into commerce, thus depressing innovative start-ups and job creation in the food industry.

Limitations of Lot or Batch numbers for traceability

The role of the “Lot Number” or “Batch Number” serves as a significant example to illustrate the consequences and challenges of applying production oriented concepts to food traceability. Most production workers are food safety oriented. When food safety is in question, workers tend to focus on lot/batch numbers in order to understand the scope of the problem since the lot/batch denotes product that was produced or treated under similar conditions using related inputs. Lot numbers are critical when the source of contamination is identified, but since they tend to be operator specific and meaningful only to a given operator within the supply chain, lot numbers are not particularly useful to traceback investigations until a specific operator’s facility is implicated. Indeed, each operator has different definitions of lots and batches and food products often become ingredients to other food products making it difficult to recreate paths through the supply chain using lot/batch codes. However, once investigators pinpoint an

operator as a likely source of contamination, that operator's specific lot/batch codes as well as all other related information such as payroll (who was working that day), storage room temperatures, cleaning records, etc. all become critically important to investigators. Therefore, while food production and food safety workers often use lot/batch codes as a central component of food traceability, it should now be clear that lot/batch codes are less than ideal for solving the logistical food traceability problem. Elimination of the use of lot/batch codes for the purposes of production management is not recommended as these data are critically important to food traceability investigations, but only when investigations lead to a specific food production operation.

Even if not used as a basis for traceability, lot/batch codes will continue to play a pivotal role in outbreak investigations once points of convergence or the source of tainted food is otherwise identified. Lot/batch codes will serve as one of the key data elements ("KDEs") for subsequent trace-forward investigations and recalls. However, in an ideal system this KDE need only exist at the operator in a form convenient to the operator.

Implementation of the Critical Tracking Event framework requires minimal and highly abstracted data (data that are meaningless to observers who are not authorized to access secured, related data) to be collected in a format that can ultimately be accessible electronically. Proprietary production data, such as

lot/batch codes need not be immediately accessible electronically since the goal is to quickly find the source(s) of convergence and/or contamination. Once convergence is identified in the supply chain, thorough investigations will require review of all pertinent documentation in all formats. The goal is to quickly focus the investigation, not to burden every operator with unnecessary data collection and associated restrictions on data formatting.

The concept of Unique Identification Codes first proposed during the Traceability Pilots required by the Food Safety Modernization Act has been met with some skepticism from the food industry, but this may be due to a lack of understanding how such codes can greatly simplify the traceability process. Opposition to the use of Unique Identification Codes has led to an unending debate over the "ideal" universal set of key data elements (KDEs) that might serve the same purpose as unique identification codes (35). Perhaps the only thing that has been concluded from all of that effort is that there is no universal set of KDEs that will work for all operators in all situations.

Logistical event based approach to traceability – Critical Tracking Events

The logistics perspective simplifies the supply chain into a series of events through which food containing "units" pass. Units may be shipping containers, pallets, cases or individual items. Therefore, advancing food traceability requires a decision as to resolution; what is the smallest and most useful unit to be

tracked in the supply chain? Since consumers typically purchase individual items in some form of retail setting, it is likely that the smallest unit received by retailers would be an aggregate of individual units, and the most common aggregation of individual units is the shipping case (typically a corrugated box containing a set number of individual items). Therefore, advancing food traceability will, at least, require some means of uniquely identifying cases. Since many individual cases may represent the same lot, there is an associated need for operators to maintain data relationships between production lots and traceability case identifiers.

Advancements in food traceability require collection and maintenance of data and data relationships and this exposes the need for involving expertise in relational data collection, storage and retrieval for advancing food traceability. Since the topic of food traceability has been viewed primarily as a food safety issue, people with expertise in food safety rather than logistics and distributed relational data have played a primary role in drafting regulatory guidelines that appear to lack sufficient expertise for flexibility, scalability, adaptability, efficiency and interconnectivity that will be necessary to achieve the goal of food traceability while offering opportunities for adding as yet unforeseen value in the marketplace (35). Ultimately, a successful global food traceability system will need all of these attributes to grow organically and improve over time.

Current Frameworks and Standards

Worldwide standards and frameworks exist to better facilitate traceability throughout the supply chain. These organizations seeks to define data standards so that data are collected in a uniform format and can be more easily shared between trading partners and other entities in the supply chain (19). Ideally, enforcement of standards should be avoided wherever possible in order to leave as many avenues for future improvements as possible. Therefore, to the extent possible, conformance with standards should not be required, but rather encouraged and/or provided as examples of modern best practices.

The CTE Framework

These realizations have led to development of a new framework concept for food traceability that offers opportunities to build upon past food traceability efforts, tools and technologies into an easily understandable and universally applicable approach. This framework concept is known as “Critical Tracking Events” (CTE) (36,37). The CTE framework provides a basis for flexibility, scalability, adaptability, efficiency and interconnectivity with little requirement for enforcing specific standards on any operator.

CTE promises to do for food traceability what Hazard Analysis Critical Control Point (HACCP) has done for food safety. The HACCP concept was developed in the 1960s to ensure that food produced for the National Aeronautics and Space Administration (NASA) was safe. The HACCP concept widely adopted by the

meat processing industry in the 1990s and is now the basis for juice and seafood regulations by the FDA (38).

The key concept for CTEs assumes each operator knows their operation best and operators are in the best position to identify those events that are critical to the overall goal of food traceability. The CTE concept simplifies the large, complex and seemingly intractable problem into a local and familiar series of events that are deemed critical to tracking items through an operation. Each operator properly identifies their own CTEs and commits to collecting a minimum set of event data for each CTE, typically consisting of a three basic data items including, unique location/Event ID (e.g. Receiving Door #2 at a given physical address), unique Item ID and date/timestamp. Each operator would collect event data from all of their CTEs and store them as they see fit in secure databases that may be accessed for query by properly authorized personnel. This simple structure leads directly to the possibility of authorized investigators being capable of generating reports showing locations, dates and times, throughout the entire supply chain, of suspect food items and ingredients, virtually instantaneously and with minimal intrusion to operators. When multiple traceback queries expose points of convergence in the supply chain, investigators can then focus their attention on the broader process and handling data of the implicated operator in order to attempt to identify the source of contamination.

As with HACCP, the CTE framework does not prescribe any particular method or technology. Operators are free to choose the methods and/or technologies that best suit their purposes. The primary strength of the CTE framework is that it is simple, flexible, scalable, secure, and efficient and does not require immediate universal participation in order benefit from the system. As operators adopt the CTE concept into their operations, the food supply chains will become increasingly traceable. Additionally, modern distributed data networks preclude any requirement for pushing or uploading CTE data to any central repository, government, database or authority. The CTE concept permits operators to maintain ownership and control of their own CTE data. Since unique traceability codes can only be linked to proprietary production related data such a lot/batch codes, CTE offers a level of security through data abstraction. This means that unique traceability codes have no inherent meaning. They simply point to a richer set of meaningful data in properly secured databases. Table 2.1 depicts the conceptual relationship between HACCP and CTE.

Data security

Generally, supply chain participants do not wish to expose proprietary data to competitors and most prefer to not be put in a position that requires trust of government agencies and/or third parties to secure such data on their behalf. It is therefore, unlikely that the vision of a central data repository controlled and/or accessible by FDA or another government entity, to which all food traceability data must be pushed, represents a sound solution (35). A similar effort was

envisioned in the 2000s by the USDA to create a national database with all farm premise locations and animal movement data to a centralized database to be used in animal disease outbreaks. Resistance from industry and trade associations quickly derailed this effort (32). In contrast, while CTE does not prescribe a particular solution for data handling, the CTE framework invites development of modern, massively distributed, highly abstracted and secure data handling methods. These modern approaches to data handling provide for operator ownership and complete control over their own data. Data abstraction provides inherent top-level security in that exposed codes do not expose meaningful information. Ideally, traceability codes should simply point to meaningful data within secured databases that can be physically and logically distributed and only accessible to properly authorized personnel with proper permissions from data owners.

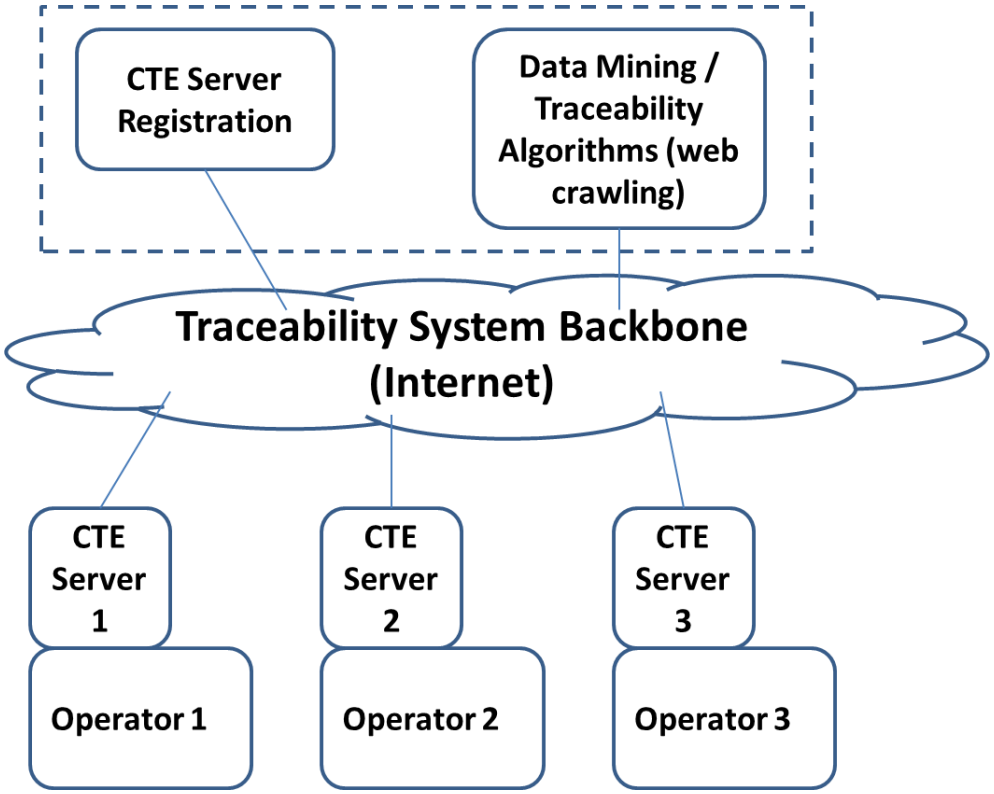
Table 2.1. Comparison of hazard analysis and critical control points (HACCP) and critical tracking events (CTEs)

HACCP	**CTEs (product tracing)**
Conduct a hazard analysis	Identify products and product inputs to be traced
Identify critical control points	Identify critical tracking events
Determine critical limits	Determine key data elements
Establish monitoring procedures	Establish data collection procedures
Establish corrective actions	Establish data storage procedures
Establish verification procedures	Conduct mock tracebacks
Ensure recordkeeping	Maintain a written record of the product tracing plan

Briefly, an example of a CTE distributed data approach involves collection and storage of CTE data at the physical location/address of the events. Operators would maintain a database on their own site or contract with a third party to host their data in much the same way that many operators contract with third parties to host their web presence or to handle critical and proprietary payroll functions (Figure 2.4).

Event data would be stored in an operator owned, controlled and secured database. By securely connecting these data servers to the Internet/cloud, investigators could use modern and increasingly advanced querying and data mining tools with appropriate authentication and permissions and determine which events suspect items traversed. In this manner, investigators will be able to rapidly identify paths of different suspect products through the supply chain with minimal interruption to operators. Rapid identification of points of convergence would permit timely and focused investigations as well as targeted recalls resulting in fewer illnesses and deaths, reduced food waste and less overall damage to industries and brands.

Figure 2.4. The CTE framework permits operators to control their own data while making them available for rapid traceback investigations without exposing proprietary data.


CTE Server Registration
Data Mining / Traceability Algorithms (web crawling)
Traceability System Backbone (Internet)
CTE Server 1
CTE Server 2
CTE Server 3
Operator 1
Operator 2
Operator 3

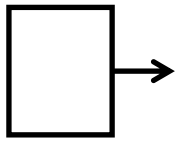
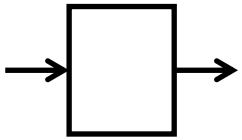
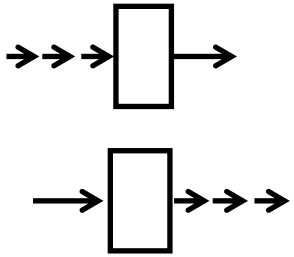
Categorization of CTEs

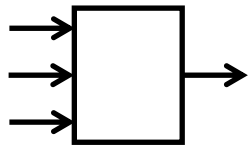
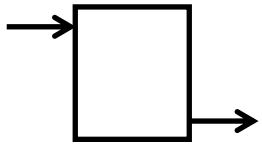
The supply chain can be divided into 4 categories of CTE's namely terminal, transfer, aggregation/disaggregation, commingling (Table 2.2).

Terminal CTEs

By definition, terminal CTEs exist on the boundary of the supply chain. Products enter and exit the traceable supply chain through terminal events. Specific situations always vary and it is the role of the operator to determine how internal linkages are made between CTE data and their actual operation. For example, consider an operation where produce is harvested from a particular field on a particular day. Harvested produce is collected in bulk and delivered by truck to an operation involving cooling, washing, sorting/grading and packing. To do this, the operator may use the point where packed cases emerge from the operation to initiate supply chain traceability. This terminal event need not be at the field of harvest so long as the operator's records are capable of leading investigators to the source field should that be necessary in the future. The terminal CTE defines entry of this food product into the supply chain. Again, the CTE could be associated with more internal data elements if the operator so chooses such as harvest worker, environmental temperature, sampling results and/or other relevant production data items. However, for the terminal CTE, the Key Data Elements are simply identification data to define "what, where, when."

Table 2.2. Four categories of critical tracking events (CTEs); terminal, transfers, aggregations/disaggregations, and commingling.

CTE Category	Description	Diagram of inputs and outputs at event type
Terminals	1. Creation, Origination 2. Disposition	
Transfers	1. Shipping 2. Receiving	
Aggregation/Disaggregation	1. Items ↔case 2. Cases ↔ pallet 3. Pallet ↔ Container, Truck, etc. 4. Container ↔ Ship, Rail, etc.	

CTE Category	Description	Diagram of inputs and outputs at event type
Commingling	1. Blend 2. Formulate 3. Bulk comingling	
	4. Rework	

Aggregation / Disaggregation CTEs

Following the Terminal CTE (which in this example occurred at the case level as product sorted and packaged), the packinghouse has identified an Aggregation CTE in their process. As cases of product are palletized, an Aggregation CTE exists and captures data identifying which cases comprise an individual pallet. When pallets are broken down, the process works in reverse in that one incoming object (pallet) results in many outgoing objects (cases).

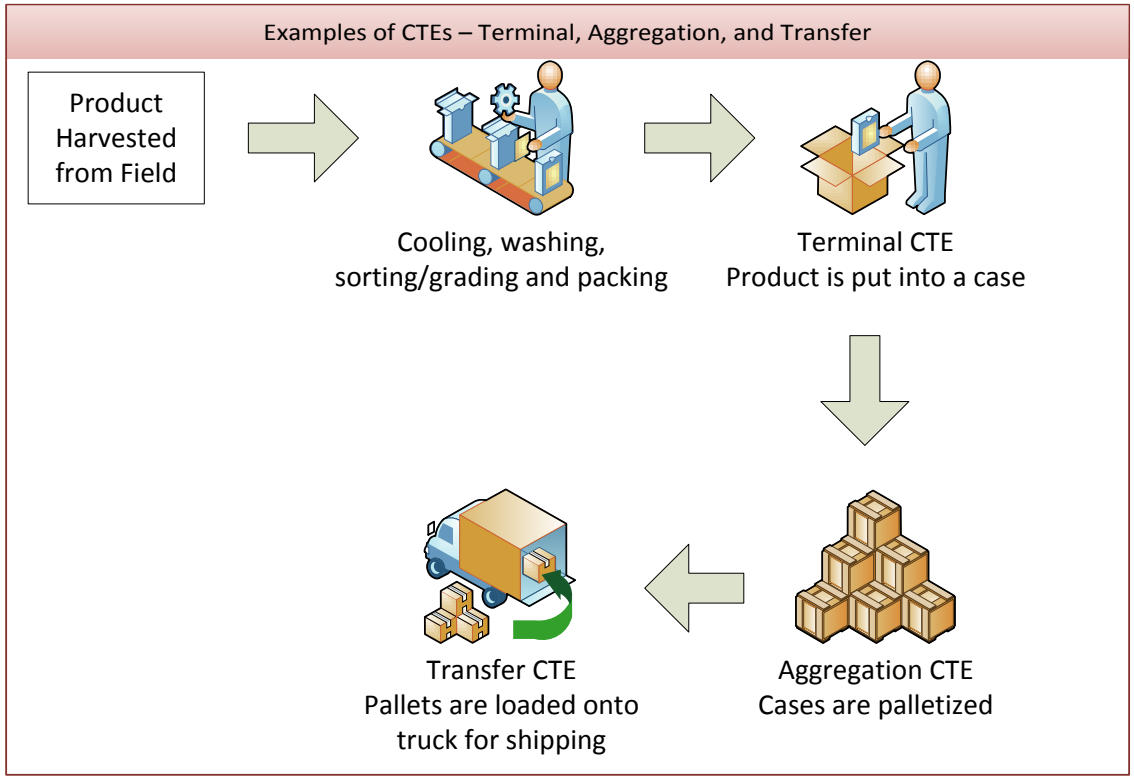
Transfer CTEs

For the hypothetical produce harvester, a transfer (shipping/receiving) CTE is created when pallets of product are loaded onto a truck for shipment.

Comingling CTEs

Comingling is usually an irreversible process where items from multiple sources of the same item and/or different items are blended together to create a new product. Comingling CTEs are typically characterized by many inputs and one output.

Figure 2.5. Example of CTEs in a simplified produce-packaging facility (terminal, aggregation , and transfer CTEs).


Examples of CTEs – Terminal, Aggregation, and Transfer
Product Harvested from Field
Cooling, washing, sorting/grading and packing
Terminal CTE
Product is put into a case
Aggregation CTE
Cases are palletized
Transfer CTE
Pallets are loaded onto truck for shipping

Lot coding considerations using CTEs

Continuing with the produce harvesting example, the operator must answer the "what?" question. In other words, "what is this item that is being introduced to the supply chain?" First explore why lot numbers are not a good choice for answering this question. The operator is free to define a "lot" in a manner that makes most sense to the operation; a shift's worth of production, a partial shift, one or more bulk truckloads, etc. Whatever the operator uses, it is highly likely that any given lot will be subsequently subdivided down the supply chain and those operators will have their own definitions for their own lots that make sense to their own operations. In the food industry, the term "lot" is more of an idea than a universally defined term. While this alone should provide a sufficient argument against the choice of lot numbers as the core data for traceability, at least two additional arguments might be made against use of lot numbers. First, lot numbers are currently elusive when dealing with an unpackaged food or an ingredient. Lot codes are often inconsistent and change meaning throughout the supply chain and therefore represent limited utility when conducting a traceback investigation. Lot codes are generally more useful when conducting a recall and therefore targeting specific production units in the supply chain. When the source of an outbreak or point of convergence is identified, investigators and operators need to know the size of the lot or lots associated with the implicated product in order to commence the subsequent investigative process and initiate the recalling of food. Using CTEs, until the source or point of convergence is identified, investigators have no need for every operator's definition of their own

lots. Investigators need an effective means to find points of convergence. Another issue with using lot numbers is that they tend to unnecessarily expose intelligence about production volumes and inventory turnover to competitors, customers and present potential food defense risks. This may or may not be deemed important to any given operator, but operators should be free to choose whether or not they wish to expose those data without being forced to do so by regulation. Therefore, while lot numbers currently are critical to the investigative process, lot numbers do not represent an ideal means for tracing items through the supply chain. Implementation of the CTE concept throughout the supply chain will obviate the need for investigators to focus primarily on lot code information as a proxy for internal traceability since case level traceability may be more widely available.

CTE codes

CTE traceability codes (Table 2.3) answer the "what?" question and should simply permit unique identification of an item in the supply chain. This means that the code need not provide rich information about the item, but rather the ability to distinguish one item from another in the supply chain. For example, it is now common to use electronic identification to pay tolls on highways. Drivers are issued a device that contains a unique code. The code itself does not contain any descriptive information about the driver or the driver's automobile. Knowledge of the code would not allow someone to know the driver's height, weight or hair or eye color. The code is simply a number that, when applied to

the right database, is able to locate the driver's database record for billing. While it is likely that descriptive information about the driver exist in the database, but only properly authorized personnel may access it.

Table 2.3. Examples of traceability codes: The codes are represented by the Unique IDs created for each combination of CTE type, name, and location.

Critical tracking events type	**Name**	**Location**	**Unique ID**
Terminal creation	Produce case packer	Washing/sorting/packaging Machine	XYZ123
Aggregation – Palletizing	Produce palletizer	End of conveyor	ABC321
Transfer – Shipping	Shipping dock door 2	Shipping dock door 2	DEF456

The example of automated toll collection applies directly to the CTE framework. The toll collection history shows only the data necessary to identify the item/car and its path in space and time (“what?” “where?”, “when?”). For food traceability, this is actually all that is required during the first traceback step of an investigation. For traceability purposes, it doesn’t matter whether the item was cheddar cheese or shredded cheese or even cheese. We simply need a record of which CTE’s handled that item with a particular unique traceability code and when (“what?”, “where?”, “when?”). Using this CTE framework, the operator associated with the terminal creation CTE for any item could, if asked, provide all of the necessary information associated with the creation of the item and its introduction to the supply chain (provided they properly associate these data with the terminal CTE). The purpose of the traceability codes is to efficiently direct investigators to the operator if associated product might be implicated in an outbreak. Therefore, the best code to be used for traceability has at least the following traits:

1. Globally unique
2. Least amount of data/bits as possible and practical
3. Simple to print, write and/or encode
4. Simple to read
5. Contains no “meaningful” information about the product or operator (i.e. doesn’t carry decodable information such as Julian date, etc.)

This lack of meaningful information mentioned in Criteria 5 above is limited to traceability code itself, which is assigned at the CTE level for database efficiency considerations. This system generated ID allows for the use of preexisting data standards such as the Serialized Global Trade Identification Number (sGTIN) which allow for the creation of a globally unique ID. Since this ID is applied to the CTE it in no way precludes or prevents the use of exiting product code information such as establishment number for USDA inspected products or lot codes being printed directly on products. This information may still be place on a product and would be captured as KDEs associated with the appropriate CTEs throughout the supply chain. The continued inclusion of this product code information will allow investigators to work quickly with the food industry to pinpoint the implicated CTEs that may be relevant in an investigation.

Technology considerations and platforms

Defining the "what"

There are a variety of coding options available that provide reasonable guarantees of uniqueness. One option that has received considerable attention was developed as a consequence of advances in RFID technology is the electronic product code (EPC). Through standardization efforts, the EPC is widely referred to as a serialized global trade identification number (sGTIN) (39). The GTIN has been used widely in the food industry and is most recognizable as the UPC code printed on most food packages (Figure 2.6).

Figure 2.6. UPC code including company prefix, item reference number, and mathematically calculated check digit.

6 14141 99999 6
U.P.C. Company Prefix
Item Reference Number
Check Digit

As with the lot number, the GTIN or UPC code does not identify a specific item, but rather a type of product in general. The sGTIN is a simple modification that adds a serial number to the GTIN to provide unique identification of items in the supply chain. GTIN codes and therefore sGTIN codes are managed globally through GS1 on a subscription basis. While GS1 is widely recognized and respected, there may be reason for an operator to wish to use another coding system now or in the future. The CTE framework simply requires uniqueness while the code exists within the supply chain. Therefore, the only practical limitation on coding systems is ensuring that others in the supply chain can read codes. It is worth noting that the GTIN was established prior to development of modern computing technologies and practices. GTIN and sGTIN codes inherently deliver meaningful data within the code such as manufacturer identification. Serialized code data may also provide insight into production volumes and rates. Exposing such data may or may not be desirable to operators especially when exposing such information is not necessary under the CTE food traceability framework. Therefore, we recommend operators consider alternative coding schemes that simply satisfy the basic CTE requirements.

Contrary to an apparently common tendency to seek enforcement of compliance with data standards and structures, readability is the only important requirement for achieving CTE based traceability. Standardized data formats may offer some limited benefits, but as long as trading partners are capable of reading codes of

other trading partners, whether similar in structure to their own or not, CTE based traceability can be accomplished. There is no technical reason that all supply chain participants use similar identifying data types or structures. Modern computer applications are very well suited for generating unique identification codes. Therefore, many readily available options exist for generating unique identification codes under the CTE framework.

Defining the "where and when"

With the ability to assign unique identification codes to items in the supply chain the question of "where?" and "when?" can be answered. Each CTE represents a repetitive event that occurs at a specific location. At worst, the location can be defined by the physical address of the operator. At best, it can be defined by the specific location within the operation where the event takes place such as a piece of processing equipment or warehouse shelf. Often, the event is defined by a particular machine that is bolted to the production floor. Extending the prior produce harvesting example (Figure 2.5), the terminal creation event might occur on the output side of the cooling/washing/sorting/packing operation where cases emerge on a take-away conveyor prior to being palletized. The operator could choose to apply pre-printed and coded labels (manually or automatically), directly print codes on cases, print and then apply labels to cases, etc. However, as codes are applied, it is possible to uniquely identify the location of the event as well as capture a date-time stamp for each occurrence.

Again, GS1 offers a data standard for uniquely identifying locations known as the global location number (GLN) (40) however, any unique identification number chosen to describe the CTE location is sufficient to achieve CTE based traceability.

As an operator identifies, instruments and documents CTE's within the operation, it becomes clearer how proprietary data remain secure while meaningless identification codes are used to point to rich sets of data within operators' secure organizations.

For the simple example of the harvest operation (Figure 2.5), three CTE's are identified including a terminal CTE (creation), and aggregation CTE (palletization) and a transfer CTE (shipping). The operator's proprietary records would describe these CTE's perhaps, as shown in Table 2.3.
The CTE event record for the Terminal Creation CTE using unique item code "789" would be shown in Table 2.4.

Table 2.4. Example of Terminal Creation critical tracking event showing the creation of an event record that records the "where, what, and when" related to the creation of a product.

Where?	**What?**	**When?**
XYZ123	789	January 31, 2013/13:50:23

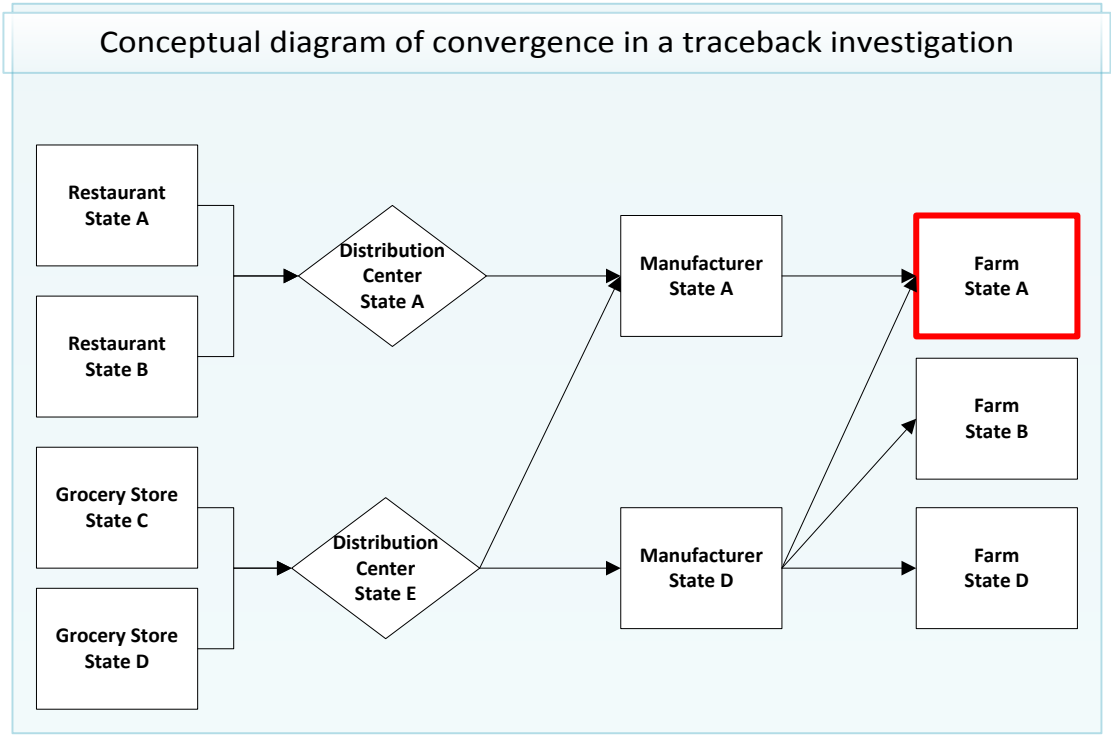
Similarly, the aggregation-palletizing CTE would record “789” being associated with the specific pallet. The shipping CTE would record the pallet being shipped. When the product arrived at the next operator, their receiving CTE would record arrival of the pallet. When the pallet is broken apart, the case identified as “789” would be recorded as being removed from the pallet, etc. There is no need to attempt to predict the path of the item through the supply chain since each operator records CTE data themselves.

Ultimately, consumers might purchase sandwiches made with produce from Case “789.” Other cases from the same production lot would have likely arrived at many other retailers. Using the unique case identifiers, investigators should be able to query the distributed CTE food traceability system essentially asking, “which CTE’s handled Case ‘789’?” The few CTE’s that actually handled the item could alert operators that an affirmative response to an investigative query must be made. At this point, the operator can provide either a quick “Yes, we handled Case ‘789’” or a more robust response with all dates, times such as “Yes we saw the item at [CTE location XYZ123] on [Date/Time].”

The dataset compiled from all CTE’s will provide a relatively immediate physical and temporal mapping of the item through the supply chain allowing investigators to quickly visualize the path and timing of multiple suspect items through the

supply chain. In many situations, the CTE framework is even capable of jumping over missing nodes, which means that the traceability system will be immediately useful and improve over time as individual operators come online with their CTE data. The CTE framework is capable of satisfying the objective to quickly focus investigator attention on points of convergence rather than working backward, serially through the cumbersome OFOB process with associated delays at each stop. (Figure 2.7)

Figure 2.7. Simple conceptual diagram of traceback investigation. In this investigation, product is traced back to a point of convergence at Farm A.


Conceptual diagram of convergence in a traceback investigation
Restaurant State A
Restaurant State B
Grocery Store State C
Grocery Store State D
Distribution Center State A
Distribution Center State E
Manufacturer State A
Manufacturer State D
Farm State A
Farm State B
Farm State D

Modern interconnectivity of computer networks via the Internet as well as cloud based storage and computing permit relational databases to exist virtually anywhere (41). Availability of this highly distributed global data infrastructure obviates the notion of a large central food traceability database. Small-scale operators could still capture these data by hand, if need be, or by the ubiquitous smart phone with appropriate applications (42).

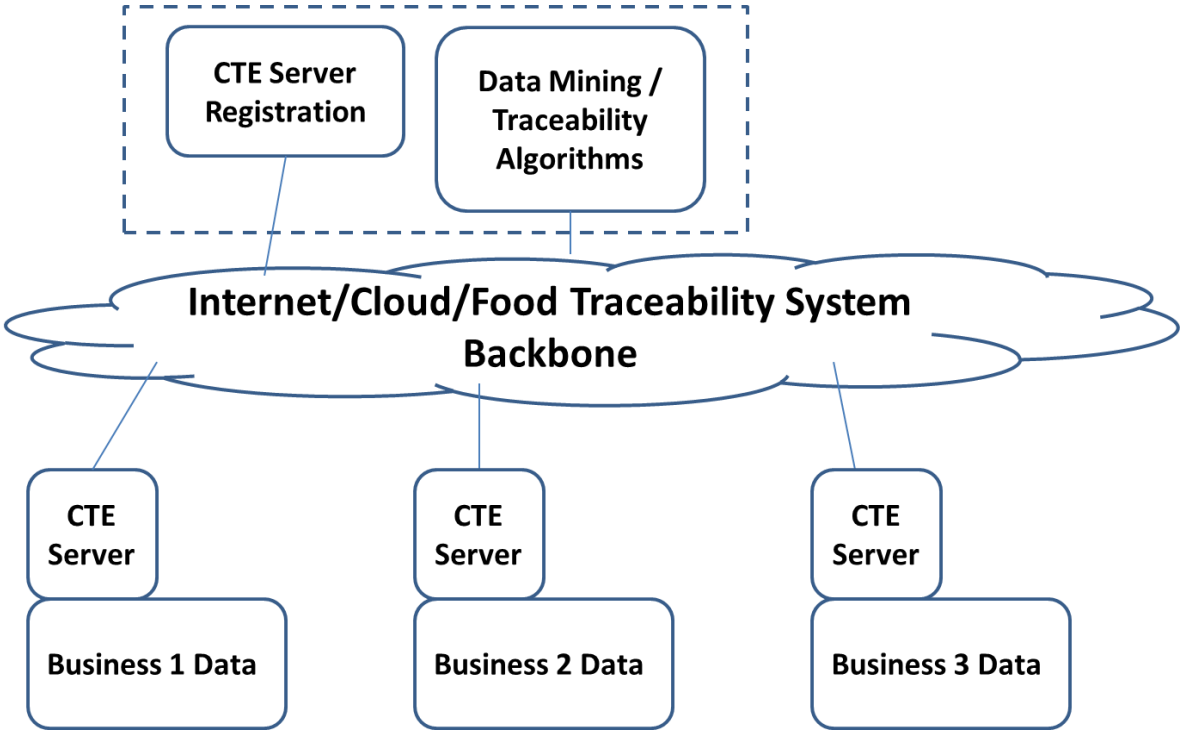
The CTE food traceability framework fits well with the modern notion of highly distributed data while promoting additional benefits of operator's maintaining ownership and control of their data as well as the associated data security that ownership and control affords.

Distributed vs. Centralized Data

While the CTE framework doesn't necessarily prescribe use of distributed data versus centralized data, it is easy to recognize the benefits of the distributed model over a centralized model. A centralized model requires that all supply chain participants conform to the central data model as well as central interface protocols. Operators would need to push data to the central database in a timely manner. Since all operators would be expected to interact with the central database, necessary changes over time would be extremely difficult to implement. Therefore, central databases tend to be inflexible, not easily scalable and therefore, become quickly obsolete. On the other hand, the distributed model permits operators to maintain ownership and control of their own data.

Simple interfaces permit investigators to make infrequent queries of data and operators are capable of controlling the scope and manner of responses. Operators maintain and upgrade their systems as appropriate without interfering with the rest of the supply chain in much the same way that companies can upgrade their own websites without interfering with the rest of the Internet. In contrast to the central database model, the distributed data model is flexible and scalable. Leveraging the modern distributed data infrastructure will permit rapid and independent expansion and utilization of CTE based food traceability.

Figure 2.8. Conceptual diagram of CTE Traceability backbone. CTEs can be identified by leveraging cloud-based search algorithms and distributed databases. Unique traceabiltiy IDs would be identified by these same search techniques and using these IDs, convergence in the supply chain is quickly identified.


CTE Server Registration
Data Mining / Traceability Algorithms
Internet/Cloud/Food Traceability System Backbone
CTE Server
CTE Server
CTE Server
Business 1 Data
Business 2 Data
Business 3 Data

Conclusion

Past outbreaks have demonstrated the need for more rapid and accurate food traceability. Using existing standards and technologies, and adopting the CTE concept of traceability would allow industry and regulators to intervene in outbreaks and prevent additional cases of foodborne illness. CTE allows for more targeted food recalls, potentially limiting the amount of unaffected food that would need to be recalled and destroyed. In turn, better traceability based on the CTE framework will result in increased public confidence in the food supply since implicated or adulterated food would be rapidly identified and removed from sale.

Chapter 3. The Use of Traceback Methods to Confirm the Source of a Multi-State *E.coli* O157:H7 Outbreak Due to In-Shell Hazelnuts

The Use of Traceback Methods to Confirm the Source of a Multi-State *E.coli* O157:H7 Outbreak Due to In-Shell Hazelnuts

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Introduction

In the United States, an estimated 63,000 cases of *E. coli* O157:H7 infection occur every year, including approximately 3,700 laboratory-confirmed cases and 20 deaths (28,43). *E. coli* O157:H7 outbreaks have been primarily associated with ground beef and leafy green vegetables, reflecting both the primary reservoir and environmental spread of the agent (43). The apparent complexity of *E. coli* O157:H7 reservoir systems results in unusual or new food vehicles, such as cookie dough and mechanically tenderized steaks, being periodically documented through outbreak investigations (44,45).

Food supply chains are integrated at the point of consumption. Complex foods may contain a combination of globally sourced and locally produced ingredients. Ingredients from a single supplier may be incorporated into hundreds of different products. These complex food systems present a considerable challenge for analytic epidemiologic investigation methods in which exposures have typically been analyzed at the level of a specific food item or commodity rather than by the source of the commodity or ingredient. This lack of detailed exposure information can limit the ability of an analytic study to identify and confirm the vehicle of outbreaks caused by commercially distributed food items.

Tracing the distribution pathway of suspect food items to their respective production sources has been a critical part of epidemiologic outbreak

investigations, providing the food exposure specificity necessary to identify the outbreak vehicle (13–15).

In February 2011, a multi-state cluster of *E. coli* O157:H7 cases with isolates of the same pulsed-field gel electrophoresis subtype (Centers for Disease Control and Prevention [CDC] *Xba*1 designation EXHX01.1159, *Bln*1 designation EXHA26.3665) was identified in Wisconsin (four cases), Minnesota (three cases), and Michigan (one case) (46).

Hypothesis-generating interviews conducted by public health agencies in each state, along with re-interviews of each case with additional specific questions about a number of food items, identified that in-shell hazelnuts was the only food item consumed by all cases. In some instances the hazelnuts were purchased as part of a mixed nut product. However, brand names for the hazelnuts were not available as in each instance they were purchased from bulk bins in grocery stores. Due to the unavailability of brand information and the higher than expected rate of reported hazelnut consumption among cases (47), investigators determined that tracing back the hazelnuts for all of the cases in an attempt to identify to a common distribution source would be the fastest and most effective way to test the epidemiological hypothesis and facilitate an effective public health intervention.

We describe here the criteria and methods used to conduct these tracebacks and consequently confirm in-shell hazelnuts as the outbreak vehicle.

Materials and Methods

Case Definition and Follow-up

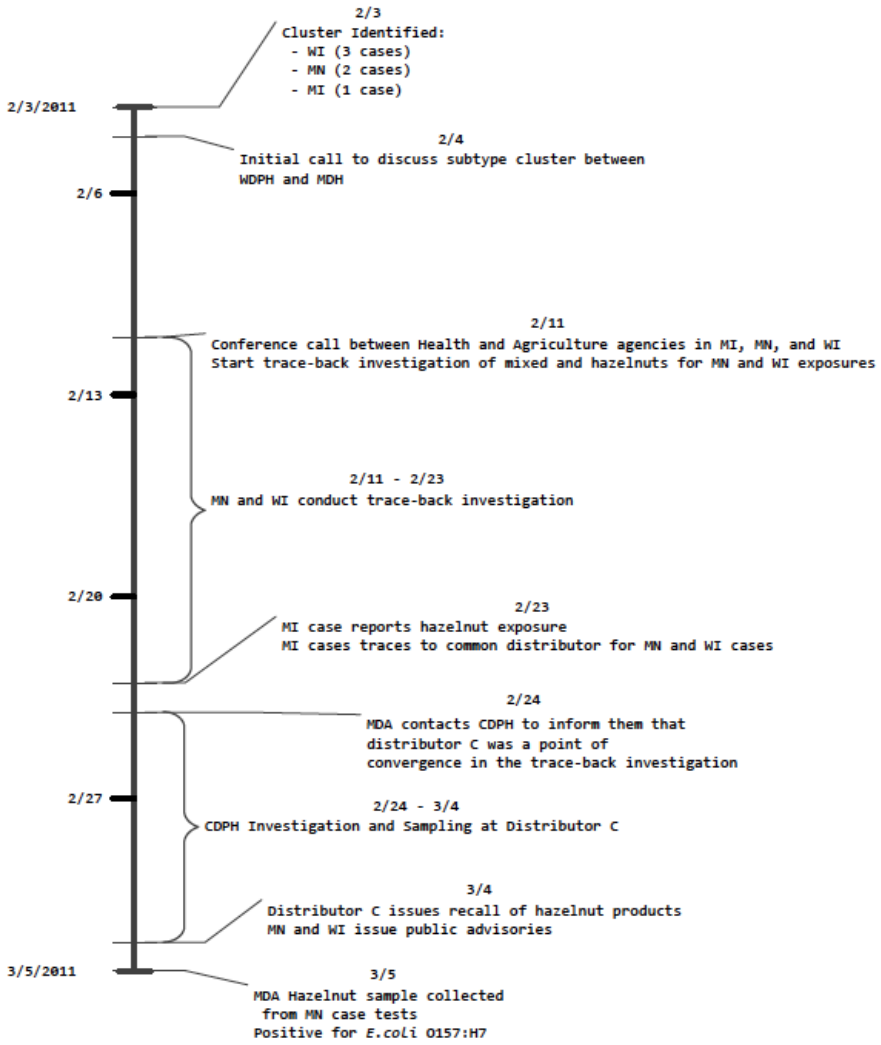
A case was defined as a person who had an *E. coli* O157:H7 isolate with the outbreak PFGE pattern (EXHX01.1159, EXHA26.3665) and who had illness onset on or after December 1, 2010. State-specific hypothesis-generating questionnaires were administered by each state, and patients were re-interviewed several times about consumption of various specific food items.

Traceback Investigation

The Wisconsin Division of Public Health (WDPH) and the Minnesota Department of Health (MDH) initially discussed the *E. coli* O157:H7 cluster on February 4, 2011 (Figure 1). On February 11, 2011, the Minnesota Department of Agriculture (MDA), MDH, WDPH, the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP), the Michigan Department of Agriculture (MDARD), and the Michigan Department of Community Health (MDCH) conducted a conference call to share updated case exposure histories, discuss suspect food items, and plan further investigation approaches. During this call it was decided that the Minnesota and Wisconsin state regulatory agencies would initiate traceback investigations of in-shell mixed nuts (in all instances the mix consisted of in-shell hazelnuts, walnuts, almonds, and brazil nuts) and in-shell

hazelnuts consumed by cases to determine if product distribution data could confirm the epidemiologic hypothesis that hazelnuts were the outbreak vehicle.

Figure 3.1. Timeline of the epidemiologic and traceback investigation starting on 3 February 2011 and concluding on 5 March 2011, when the outbreak PFGE pattern was identified from a hazelnut sample collected from a case patient's home. Agency acronyms: WDPH, Wisconsin Department of Public Health; MDH, Minnesota Department of Health; MDA, Minnesota Department of Agriculture; CDPH, California Department of Public Health.


2/3
Cluster Identified:
- WI (3 cases)
- MN (2 cases)
- MI (1 case)
2/3/2011
2/4
Initial call to discuss subtype cluster between WDPH and MDH
2/6
2/11
Conference call between Health and Agriculture agencies in MI, MN, and WI
Start trace-back investigation of mixed and hazelnuts for MN and WI exposures
2/13
2/11 - 2/23
MN and WI conduct trace-back investigation
2/20
2/23
MI case reports hazelnut exposure
MI cases traces to common distributor for MN and WI cases
2/24
MDA contacts CDPH to inform them that distributor C was a point of convergence in the trace-back investigation
2/27
2/24 - 3/4
CDPH Investigation and Sampling at Distributor C
3/4
Distributor C issues recall of hazelnut products
MN and WI issue public advisories
3/5/2011
3/5
MDA Hazelnut sample collected from MN case tests
Positive for E.coli O157:H7

MDA contacted the California Department of Public Health (CDPH) to inform them that a distributor in California (distributor C) was a point of convergence in the traceback investigation. On February 25, CDPH conducted an inspection of this distributor and collected invoices and other records to identify the source of this distributor's in-shell mixed nut and hazelnut products.

Record Collection

Table 3.1 lists the type of information that was collected by MDA, WDACTP, MDARD and CDPH (48). Records during this traceback investigation were collected in-person by field investigation staff and remotely by phone, e-mail or fax. The records collection time window was based on case exposure information, product shelf life, and product residence time in the supply chain.

Each regulatory agency obtained invoices from each retailer where a case had reported purchasing either in-shell mixed nut or in-shell hazelnut products. A traceback target time frame from November 1, 2010 to December 31, 2010 was established, and invoices for all bulk in-shell nuts within this time frame were requested from each retailer.

The MDARD food inspection staff visited the Michigan retail store to obtain invoices. WDATCP and MDA contacted retail locations and distributors both in person and by telephone, and invoices were obtained in person, by fax or e-mail.

Table 3.1: Type of records and information that should be collected during a traceback investigation.

Information Type	Type of records or information
Record Collection	• Examples of records that typically need to be collected include, but are not limited to: invoices, shipping and receiving records, bills of lading, inventory record queries, label information, packaging type and size, lot codes, UPC or GTINs, and production dates.
Product ordering and shipping	• How and when product is ordered? • How much of the product is used or shipped daily? • What is done if the establishment runs out of product before another shipment is received (e.g., purchase from grocery store, request more from supplier, etc.)? • How are deliveries and receipt dates recorded? • Compare the shipping dates to the dates received; Determine suppliers during the time period of interest, including cash transactions. • What is the transportation time from supplier(s) to the establishment? • Was the product re-packed during distribution?
Product Storage and Handling	• How is the product unloaded and added to existing inventory? • Is the suspect food item-used as an ingredient in preparation or manufacture of another food item? • How is stock inventory recorded? • How are partial cases/containers accounted for if carryover is recorded? • What does each inventory number represent? • Review the standard procedures for stock rotation and determine if the facility is capable of internal traceability or follows a first-in-first-out (FIFO) model.

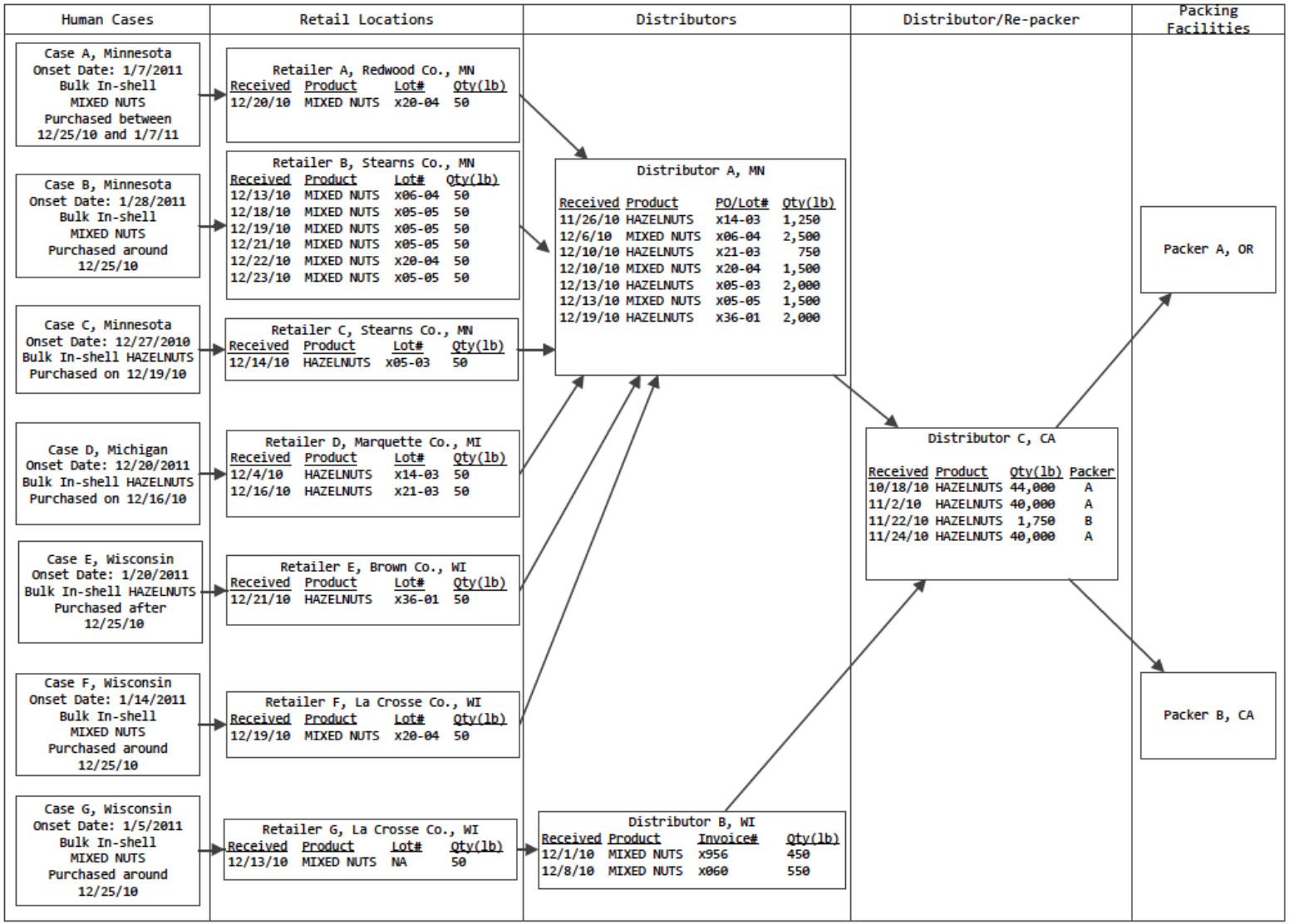
MDA investigators contacted a distributor in Minnesota by telephone and e-mail and requested invoice and purchase order (PO) records pertaining to this distributor's source of in-shell nuts that would have shipped to six retail stores where case-patients had purchased in-shell hazelnuts or in-shell mixed nuts. WDATCP contacted a Wisconsin distributor by telephone and e-mail and requested invoice and purchase order (PO) records and bills-of-lading pertaining to this distributor's source of in-shell nuts that corresponded to product shipped to a retail store where a case-patient had purchased in-shell mixed nuts.

Wisconsin and Minnesota investigators analyzed product distribution information to identify shipments most likely associated with illness, based on case-reported purchase and consumption dates.

An iterative approach was used in Minnesota to collect traceback information, similar to that used in epidemiological investigations (21,49). This approach, as it applies to traceback investigations, involves confirming product distribution and receipt backwards through the supply chain to confirm that product that was shipped was actually received. This involved verifying that documents related to incoming shipments matched the quantities and descriptions of the outgoing shipments, one step back in the supply chain. Where discrepancies were identified, investigators contacted both entities in the supply to seek clarification.

A traceback diagram that included case onset dates, case purchase dates, product description, quantities, shipment and receipt dates, invoice and PO numbers, and notes on case exposures or product handling practices was constructed (Figure 3.2). Figure 3.2 has been simplified for publication to include only the shipments and product exposures most likely to have been associated with human illnesses.

Figure 3.2. Traceback diagram for E. coli O157:H7 1102WIEXH-1 cluster investigation of seven cases in three states. The hazelnuts were traced back to two packing facilities and did not undergo further processing at the distributor or retail level. The mixed nuts were made by distributor C and included the same hazelnuts from the packing facilities. Distributor A assigned unique identifiers based on purchase order number (PO #), which created internal traceability and facilitated rapid traceback. This figure depicts shipments limited to 2 weeks prior to a case's approximate purchase date and does not represent all of the hazelnuts or mixed nuts distributed during the outbreak investigation.


Human Cases
Retail Locations
Distributors
Distributor/Re-packer
Packing Facilities
Case A, Minnesota
Onset Date: 1/7/2011
Bulk In-shell
MIXED NUTS
Purchased between
12/25/10 and 1/7/11
Case B, Minnesota
Onset Date: 1/28/2011
Bulk In-shell
MIXED NUTS
Purchased around
12/25/10
Case C, Minnesota
Onset Date: 12/27/2010
Bulk In-shell HAZELNUTS
Purchased on 12/19/10
Case D, Michigan
Onset Date: 12/20/2011
Bulk In-shell HAZELNUTS
Purchased on 12/16/10
Case E, Wisconsin
Onset Date: 1/20/2011
Bulk In-shell HAZELNUTS
Purchased after
12/25/10
Case F, Wisconsin
Onset Date: 1/14/2011
Bulk In-shell
MIXED NUTS
Purchased around
12/25/10
Case G, Wisconsin
Onset Date: 1/5/2011
Bulk In-shell
MIXED NUTS
Purchased around
12/25/10
Retailer A, Redwood Co., MN
Received Product Lot# Qty(lb)
12/20/10 MIXED NUTS x20-04 50
Retailer B, Stearns Co., MN
Received Product Lot# Qty(lb)
12/13/10 MIXED NUTS x06-04 50
12/18/10 MIXED NUTS x05-05 50
12/19/10 MIXED NUTS x05-05 50
12/21/10 MIXED NUTS x05-05 50
12/22/10 MIXED NUTS x20-04 50
12/23/10 MIXED NUTS x05-05 50
Retailer C, Stearns Co., MN
Received Product Lot# Qty(lb)
12/14/10 HAZELNUTS x05-03 50
Retailer D, Marquette Co., MI
Received Product Lot# Qty(lb)
12/4/10 HAZELNUTS x14-03 50
12/16/10 HAZELNUTS x21-03 50
Retailer E, Brown Co., WI
Received Product Lot# Qty(lb)
12/21/10 HAZELNUTS x36-01 50
Retailer F, La Crosse Co., WI
Received Product Lot# Qty(lb)
12/19/10 MIXED NUTS x20-04 50
Retailer G, La Crosse Co., WI
Received Product Lot# Qty(lb)
12/13/10 MIXED NUTS NA 50
Distributor A, MN
Received Product PO/Lot# Qty(lb)
11/26/10 HAZELNUTS x14-03 1,250
12/6/10 MIXED NUTS x06-04 2,500
12/10/10 HAZELNUTS x21-03 750
12/10/10 MIXED NUTS x20-04 1,500
12/13/10 HAZELNUTS x05-03 2,000
12/13/10 MIXED NUTS x05-05 1,500
12/19/10 HAZELNUTS x36-01 2,000
Distributor B, WI
Received Product Invoice# Qty(lb)
12/1/10 MIXED NUTS x956 450
12/8/10 MIXED NUTS x060 550
Distributor C, CA
Received Product Qty(lb) Packer
10/18/10 HAZELNUTS 44,000 A
11/2/10 HAZELNUTS 40,000 A
11/22/10 HAZELNUTS 1,750 B
11/24/10 HAZELNUTS 40,000 A
Packer A, OR
Packer B, CA

Laboratory Investigation

A sample of in-shell bulk hazelnuts was collected from one case household and tested by the MDA using the standard method, which involves a PCR screen followed by culture confirmation incorporating IMS isolation techniques (44). One 50-pound bag of hazelnuts and one 50-pound bag of walnuts were collected from the California distributor by the CDPH during on onsite inspection. Wisconsin DATCP collected in-shell hazelnuts from a case household as well as a 50-pound bag of in-shell mixed nuts from a Wisconsin distributor that was returned after the California distributor announced its recall (50).

Results

Traceback Investigation

Tracebacks were completed for seven of the eight cases linked to the cluster (Cases A-G, Figure 3.2); the eighth case reported an exposure to the implicated hazelnuts but was detected in Wisconsin after the products had been recalled. Each case reported either an in-shell mixed nuts or in-shell hazelnut exposure, and no case reported consuming both products prior to illness onset. Four (57%) cases reported the purchase of bulk in-shell mixed nuts and three (43%) reported purchase of bulk in-shell hazelnuts.

The purchase dates reported by the cases ranged from December 16, 2010 to January 7, 2011, although five cases reported purchase dates around December

25, 2010. Each case reported purchasing nuts from a separate retailer (retailers A-G).

Six retailers (86%) reported purchasing nuts from a common distributor (distributor A). The one (14%) retailer who did not receive in-shell nuts from distributor A, received in-shell mixed nuts from a distributor in Wisconsin (distributor B). Both distributor A and B received 100 percent of their in-shell mixed and hazelnuts from a common third distributor C during the investigation timeframe.

Among the six retailers that received in-shell mixed nuts or in-shell hazelnuts from distributor A in the two weeks prior to case purchase, one (14%) lot of in-shell mixed nuts was shipped to multiple retailers (A, B, and F). This common lot (Lot x20-04 in Figure 3.2) was in three (75%) retail locations two weeks prior to patient purchase dates and was the only shipment to two (50%) of the retail locations associated with mixed nut exposures. The source of the hazelnuts in Lot x20-04 of mixed nuts could not be directly traced to an incoming shipment of hazelnuts at the California distributor (distributor C) due to a lack of internal traceability. However, based on the documented first-in-first-out (FIFO) product handling practices at distributor C, it is likely that the hazelnuts received on November 22, 2010 from packer B or on November 24, 2010 from packer A were

the likely source. Given the volume of hazelnuts received from packer A, it is more likely that packer A was the source of the contaminated hazelnuts.

There were no common lots of in-shell hazelnuts shipped to all retailers during the two weeks prior to case purchase dates. Based on shipments to retailers C, D, and E, it is likely that product received at distributor A on or after December 10, 2010 was most likely to be associated with illness, and these shipments also traced-back to product received at distributor C on November 22, 2010 and November 24, 2010.

Initially, retailer C denied that distributor A supplied any hazelnuts to the store during the investigation time frame. After repeated phone interviews with the quality assurance (QA) manager for retailer C and the QA manager for distributor A, a single shipment of hazelnuts to retailer C occurring on December 14, 2010 was identified.

Ninety-eight percent (124,000 pounds) of in-shell hazelnuts that distributor C distributed during the target timeframe were received from packer A while less than two percent (1750 pounds) came from packer B (a single shipment received on November 22, 2010). A specific hazelnut grower was not identified during the traceback investigation because packer A did not provide records to the regulatory agencies. However, during the course of the investigation packer A

indicated that between 20 and 60 growers might have provided product that shipped to Distributor C in the timeframe of interest and Packer A sourced only domestically harvested hazelnuts.

Some 50-pound bulk bags of hazelnuts at distributor C received from packers A and B were used to make the in-shell mixed nuts shipped to distributors A and B. Those hazelnuts not used to manufacture mixed nuts at distributor C followed an approximate FIFO pattern of shipment. Records at distributor C were not of sufficient detail to link incoming shipments of hazelnuts from packers A and B to outgoing shipments of mixed nuts and hazelnuts to distributors A and B.

Recall Announcement

On March 4, 2011 distributor C issued a voluntary recall of all hazelnuts and mixed nut products distributed from November 2 to December 22, 2010. Recalled product was distributed to stores in seven states: Minnesota, Iowa, Michigan, Montana, North Dakota, South Dakota, and Wisconsin.

Regulatory and health agencies in Minnesota and Wisconsin issued press releases on March 4, 2011 to inform the public. All persons who had recalled in-shell hazelnuts were encouraged to discard them or return them to the store. MDA and WDATCP provided a list of stores where recalled product was sold based on distribution records obtained during the traceback investigation.

Laboratory Investigation

On March 5, 2011, the MDA laboratory reported isolation of *E. coli* O157:H7 from bulk in-shell hazelnuts collected from a case patient's home; on March 7, the isolate was determined to match the outbreak pattern by PFGE and MLVA. The outbreak strain of *E. coli* O157:H7 was also isolated from an intact in-shell mixed nut sample collected from an intact 50-pound bag collected from distributor B by WDATCP on March 11, 2011. WDATCP also isolated Shiga toxin-producing *E. coli* (STEC) O64:H34 from an intact in-shell mixed nut sample collected from a 50-pound bag from distributor B. CDPH isolated the outbreak PFGE subtype of *E.coli* O157:H7 from an in-shell mixed nut sample collected from an intact 50-pound bag from distributor C. Because of inadequate recordkeeping at distributor C, investigators could not definitively link positive product samples to a particular incoming shipment from packer A or B. The FIFO practices and quantity of product received suggested that the 40,000 pound shipment from packer A to distributor C on November 24, 2010 likely contained the contaminated bolus of hazelnuts.

Discussion

This was an outbreak of *E. coli* O157:H7 infections associated with bulk in-shell hazelnuts sold at retail food locations in Minnesota, Wisconsin, and Michigan. This is the first recognized *E. coli* O157:H7 outbreak associated with nuts. However, previous *Salmonella* outbreaks or recalls have been associated with almonds, pistachios, and peanuts (6,7,46,51–53).

Regulatory agencies have historically conducted tracebacks to determine the source of a product after laboratory confirmation of the etiologic agent in food or after the food item was epidemiologically associated with illness in an analytic study. This outbreak demonstrates the usefulness of starting a traceback investigation before the food can be definitively implicated, with the goal of confirming a suspected association by identifying a common source via a point of convergence in the food supply. By starting earlier in the course of an investigation than is traditional, this type of traceback can provide meaningful information that can shorten the course of the investigation and lead to an earlier public health intervention.

The following criteria were used to determine if a traceback investigation was warranted as part of the epidemiologic investigation:

1. A PFGE subtype cluster of cases likely represented a common source outbreak;
2. Cases occurred in multiple locations or jurisdictions (in this instance, multiple states);
3. Interviews of case-patients revealed no obvious point-source exposures in common (e.g., they did not eat at the same restaurant or attend the same event), suggesting that the outbreak vehicle was a commercially distributed food item; and

4. A suspect food vehicle was identified and the frequency of exposure among cases provided a strong hypothesis that could be directly tested by identifying a common production source for exposed cases.

The following criteria were used to determine which mixed nut and hazelnut exposures should initially be traced:

1. The likelihood that the exposure was truly the exposure of interest for a case;

2. The availability of clear, documented details on the exposure; and

3. Geographic and/or temporal dispersion of case exposures with the goal of identifying multiple food distribution chains during the traceback.

In this outbreak a common PFGE subtype cluster was identified, cases occurred in three states with unique retail exposures, bulk nuts were epidemiologically suspected and identifying a common source of production was determined to be the fastest and most effective way to test the epidemiological hypothesis. Each case represented a unique retail exposure and all were traced with the same priority.

Bulk in-shell nuts, like many produce items, were not labeled and therefore the consumer could not report brand information when interviewed. In order to accurately identify commonalities associated with the hazelnut exposures, a

traceback investigation was required. Because identifying a common distribution source was the most direct way to test the epidemiological hypothesis and maximize the public health intervention, the tracebacks needed to be conducted rapidly. The outbreak strain of *E. coli* O157:H7 was ultimately isolated from in-shell hazelnuts and mixed nuts containing in-shell hazelnuts. However, laboratory confirmation occurred after the tracebacks confirmed the epidemiologic hypothesis and thereby enabled investigators to implicate hazelnuts and prompt the recall and public advisories.

Multi-state outbreaks in which cases are not uniquely associated with a single retailer suggest that the source is a commercially distributed food and that the source is not primarily associated with on-site environmental or food-worker contamination. Although food workers and environmental contamination need to be addressed, in these types of outbreaks priority should be given to rapid tracebacks through record collection related to product receipt and distribution in order to identify common suppliers throughout the supply chain.

The Importance of Internal Traceability

Distributor A possessed good internal data systems and provided accurate summary reports of their complete distribution. Using the iterative investigation approach, a review of distributor A's records identified a shipment of in-shell hazelnuts to retailer C that was originally and repeatedly denied by retailer C during the initial stage of the investigation. This shipment was significant

because it was the only shipment received by retailer C of in-shell hazelnuts and represented the exposure associated with the related case's illness as well as the positive home sample. This demonstrates the importance of re-interviewing companies and re-analyzing the distribution data when there's an apparent discrepancy.

A common source was identified in this investigation by defining implicated shipments corresponding to case purchase dates and tracing these shipments back from retailers through distributors to a repackaging and distribution operation (distributor C). While this operation (distributor C) was not likely the original source of adulteration, it did represent a common point of convergence for all cases in terms of product distribution. Distributor C received over 99 percent of their in-shell hazelnuts from packer A, located in Oregon. Ninety-nine percent of domestically harvested hazelnuts are grown in Oregon (54).

Product handling practices at distributor C complicated the traceback investigation. Distributor C did not maintain records that would allow investigators to link an incoming shipment of bulk nuts to an outgoing lot of finished product when manufacturing mixed nuts.

Packer A did not maintain adequate internal traceability records to allow investigators to adequately identify a subset of farms that provided hazelnuts

during the timeframe of interest. Without access to these records, investigators were unable to conduct environmental assessments of the farms that supplied packer A to identify possible sources of contamination or adulteration.

The lack of internal traceability within the food processing industry and among distributors is not uncommon (1,55). The passage of the federal Food Safety Modernization Act in January 2011 increases recordkeeping requirements and may improve internal traceability in the future (18).

Distributor A maintained internal traceability and assigned a unique lot number to all incoming products based on the purchase order and item number of incoming product (Figure 3.2). This internal traceability allowed investigators to trace product in retail stores directly back to specific incoming shipments from distributor C to distributor A. If this level of traceability were available throughout the entire supply chain it would be possible to easily identify a farm or producer as the source of contamination. Specifically, the positive hazelnuts collected from the Minnesota case household came from a single identifiable shipment to retailer C on December 14, 2010. Because this was the only shipment to this location and the hazelnuts tested positive, complete supply chain traceability would have identified the farm where the product was grown and harvested.

This outbreak investigation illustrates the importance of collaboration between epidemiologists and regulatory officials within individual states, and between states. Regular conference calls were held among MDA, MDH, WDATCP, WDPH, MDARD, MDCH, CDC and FDA to discuss common exposures among cases and share traceback information as the evidence was collected and developed. Given the small number of cases, the likelihood that a single state could have implicated in-shell hazelnuts was small.

Similarly, detailed communication among regulatory agencies increased the speed and accuracy of the investigation. MDA was in regular communication with CDPH once distributor C had been identified during the traceback investigation. CDPH's inspection of distributor C and record collection prompted a recall of the adulterated product on March 4, 2011, three weeks after the initial conference call between MDA and WDPH (Figure 3.1).

Hazelnuts are mechanically harvested from the ground. Processing practices may vary by facility, where some may be treated with an antimicrobial wash prior to the drying process. The risk of fecal or environmental contamination of the outside of the hazelnut is highly plausible. Previous outbreaks of fresh produce have been associated with fecal contamination of fields by wild animals and domestic ruminants (27,56). In this instance, it's plausible that feces from wild deer or domestic cattle grazing in the orchards contaminated the surface of the

hazelnuts prior to harvesting. No published data exist on the survivability of *E. coli* O157:H7 on in-shell nuts, but the traceback evidence suggests that the organism remained viable for at least three months from the time of initial distribution to when the home sample tested positive on March 5, 2011. There is evidence that *Salmonella* can persist for days to weeks on nutshells and in orchard soils (57–59). In pecans and almonds, *Salmonella* can infiltrate a damaged shell and remain viable in the kernel for over a year after drying (60,61).

This investigation was timely and resulted in the recall of adulterated product, but it was limited by inadequate recordkeeping by distributor C and packer A, which did not allow for the identification of the farms that were the ultimate source of contamination. Without access to this information, investigators were unable to physically investigate and assess potential sources of contamination.
Better recordkeeping and internal traceability within the food industry will improve the timeliness and accuracy of future traceback investigations. The hazelnut industry benefited from implicated product being traced to a single distributor and a limited number of packers, rather than hazelnuts in general. Several recent outbreaks associated with tomatoes, spinach, and sprouts have seen consumer advisories that target an entire commodity group (3,27,62). Importantly, this outbreak demonstrated how a collaborative multi-jurisdictional rapid traceback investigation significantly reduced the time required to identify the source of

adulterated product and initiate a meaningful public health intervention. The isolation of pathogenic STEC from recalled product suggests that additional human illnesses were prevented as a result of the investigation and subsequent recall.

Chapter 4. The Use of Global Trade Item Numbers (GTIN) in the Investigation of a *Salmonella* Newport Outbreak Associated with Blueberries – Minnesota, 2010

The Use of Global Trade Item Numbers (GTIN) in the Investigation of a *Salmonella* Newport Outbreak Associated with Blueberries – Minnesota, 2010

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Introduction

In the United States, an estimated 1,027,000 cases of nontyphoidal *Salmonella enterica* infection occur every year, including approximately 42,000 laboratory-confirmed cases and 378 deaths (28). Nontyphodial *Salmonella* outbreaks have been associated with a wide variety of foods including fresh produce, manufactured foods and milk and meat products (3,4,6,7,53,63–65). Similarly, outbreaks due to *Salmonella enterica* serotype Newport have been associated with a wide variety of foods; produce items (e.g., tomatoes, alfalfa sprouts, mangos, lettuce) have frequently been implicated (5,66–68).

Produce in the food supply chain often moves without an associated lot code or other identifying information (69). Given the relative anonymity of fresh produce in the supply chain, consumers often cannot remember a brand name if they become ill after consumption and no longer retain the product packaging. The use of shopper-card information associated with consumer purchases can assist public health and regulatory investigators in identifying specific products likely associated with illness since all transactional purchase data are collected and stored against a shopper-card number. The use of these data has been valuable in investigating past foodborne illness outbreaks (2,64,70).

On August 4, 2010, the Minnesota Department of Health (MDH) Public Health Laboratory (PHL) notified MDH epidemiology staff of two *Salmonella* Newport isolates, from clinical samples, collected two days apart, with indistinguishable pulsed-field gel electrophoresis (PFGE) patterns (Centers for Disease Control and Prevention [CDC] *Xba*I designation JJPX01.0041) identified through routine surveillance. Over the next two days, the MDH PHL identified three additional isolates with the same pattern. All five specimens were from females over 50 years of age from the same small city in northwestern Minnesota. A search of the national PulseNet database revealed that 19 additional case isolates with this PFGE pattern had been detected in 8 other states, almost exclusively in the Southeastern United States where *S*. Newport is endemic.

We describe here the investigation of the outbreak, which identified fresh blueberries as the cause. Specifically, the use of supplier-specific 12-digit Global Trade Item Numbers (GTINs) (71) identified a single blueberry grower linked to cases, corroborating the results of an analytic study which statistically implicated blueberries.

Materials and Methods

Epidemiologic Investigation

Methods for *Salmonella* surveillance used by MDH have been well documented (49). Briefly, submission of clinical isolates to MDH PHL is required by state rule, all isolates are subtyped by PFGE in real time, all cases are interviewed as soon

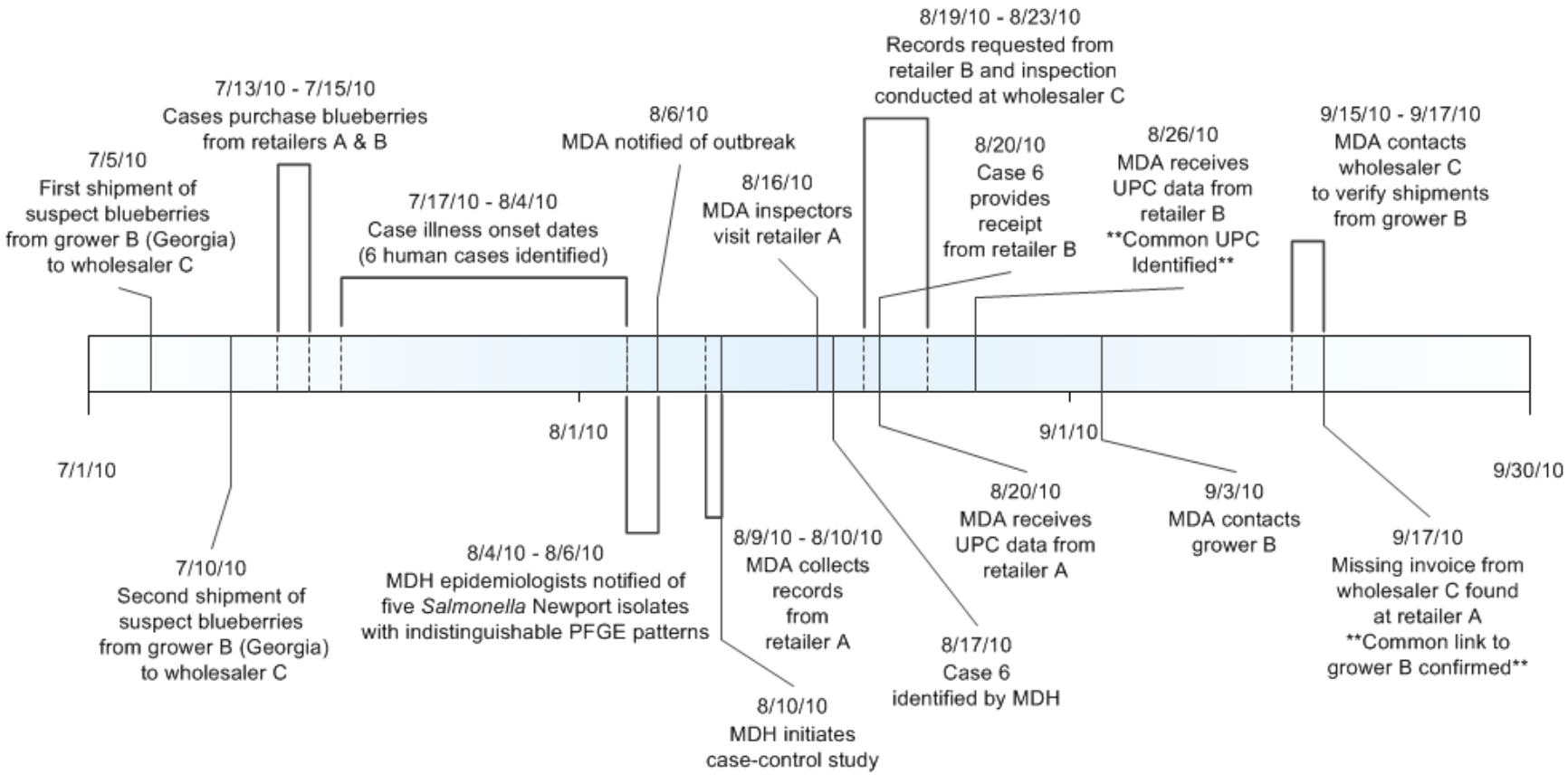
as possible with a detailed exposure questionnaire about exposures in the 7 days prior to symptom onset (including brand names, varieties, and point of sale or service locations of foods), and clusters are investigated using an iterative model.

In this outbreak, a case was defined as a person from whom *Salmonella* Newport with the outbreak PFGE pattern was isolated from a specimen collected after July 15, 2010. Hypothesis-generating interviews were conducted by MDH, and patients were re-interviewed several times about consumption of various specific food items and other potential common source exposures.

On August 6, the Minnesota Department of Agriculture (MDA) was notified of the *S.* Newport cases, and requested MDH to obtain purchase history information from retailer A based on shopper-card numbers provided by consenting cases (Figure 4.1). Case consent was obtained at the time of the telephone interview; cases voluntarily provided shopper-card information to MDH with the knowledge that it would be shared with MDA for the purpose of accessing purchase records. A case-control study was initiated on August 10 to evaluate food items frequently reported by cases. Four controls for each case were recruited using phone lists generated using reverse-directory of addresses in the same geographic area as the case's home. Controls were restricted to females over 50 years of age who reported no diarrhea or vomiting since the week preceding the matched case's illness onset date. Matched odds ratios were calculated for each of the 13 food

items on the questionnaire; each analysis excluded enrollees who could not recall whether or not they were exposed to that item. Statistical analyses were conducted using SAS software (SAS Institute, Cary, NC) with $p < 0.05$ considered to represent a significant exposure association.

Figure 4.1. Timeline of the *Salmonella* Newport outbreak and traceback investigation. Shipments of the suspected blueberries were shipped from Georgia to Minnesota on July 5, 2010. The investigation definitively determined the source of the blueberries on September 17, 2010, after point-of-sale data were used to determine that a critical invoice had not been provided concurrently by retailer A and wholesaler C earlier in the investigation.


8/19/10 - 8/23/10
Records requested from retailer B and inspection conducted at wholesaler C
7/13/10 - 7/15/10
Cases purchase blueberries from retailers A & B
8/6/10
MDA notified of outbreak
9/15/10 - 9/17/10
MDA contacts wholesaler C to verify shipments from grower B
8/20/10
Case 6 provides receipt from retailer B
8/26/10
MDA receives UPC data from retailer B
Common UPC Identified
7/5/10
First shipment of suspect blueberries from grower B (Georgia) to wholesaler C
7/17/10 - 8/4/10
Case illness onset dates (6 human cases identified)
8/16/10
MDA inspectors visit retailer A
8/1/10
9/1/10
7/1/10
9/30/10
8/20/10
MDA receives UPC data from retailer A
9/3/10
MDA contacts grower B
9/17/10
Missing invoice from wholesaler C found at retailer A
Common link to grower B confirmed
7/10/10
Second shipment of suspect blueberries from grower B (Georgia) to wholesaler C
8/4/10 - 8/6/10
MDH epidemiologists notified of five Salmonella Newport isolates with indistinguishable PFGE patterns
8/9/10 - 8/10/10
MDA collects records from retailer A
8/17/10
Case 6 identified by MDH
8/10/10
MDH initiates case-control study

Traceback investigation

MDA initiated a traceback investigation to collect documents, records, and information using previously described criteria (16). To collect information quickly, records and data were requested using the phone or e-mail whenever possible, but it was also necessary to visit some of the implicated facilities to obtain additional records. Shopper-card information was requested to link product purchases to specific dates in order to verify information provided by cases during the epidemiological interviewing process. Verbal consent was obtained from cases by MDH to share shopper-card information with MDA.

On August 9, purchase histories for five shopper-cards were requested from retailer A; these five card numbers corresponded to four cases (one case had two shopper-card numbers). Copies of purchase receipts within a month prior to illness onset from cases were provided to MDH and forwarded to MDA. While waiting for retailer A to provide shopper-card information, on August 10 MDA also requested invoices for all blueberries received at retailer A between June 26 and July 23. On August 16, an MDA inspector conducted an onsite inspection of retailer A to verify that contamination of the blueberries was unlikely to have occurred at retailer A.

MDA also interviewed retailer A to determine the typical timeframe between when blueberries are received at the store and when they are sold or have exceeded their expiration date.

On August 19, following the identification of a sixth case by MDH, MDA contacted a second retailer (retailer B) to obtain invoice and blueberry handling information for approximately two weeks prior to the case's known purchase date. On August 19, retailer B provided invoices for blueberries received from wholesaler C between July 1 and July 12, 2012.

An onsite inspection at wholesaler A, a primary supplier to retailer A, was conducted on August 19, 2010 to verify that contamination of the suspect blueberries was unlikely to have occurred at wholesaler A (Figure 4.1). Based on the UPC sales reports provided by retailer A, on August 23 an MDA investigator called retailer A to understand how these UPCs are entered and recorded.

Once UPC GTIN data was collected from retailer A, an online database of trade-item ownership (http://gepir.gs1.org) was accessed by investigators. Global Electronic Party Information Registry (GEPIR) is a unique, internet-based service that gives access to basic contact information for companies that are members of GS1. GS1 is an international not-for-profit standard setting organization

responsible for the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. These member companies use GS1's globally unique numbering system to identify their products, physical locations, or shipments. By entering a product bar code number into GEPIR, one can find the owner of that barcode's contact information. Physical location numbers and shipment numbers can also be used as search criteria in this system (72).

Results

Epidemiological Investigation

During hypothesis-generating interviews of the first five cases, none of the cases reported any common restaurants, gatherings, events, civic groups, or faith-based organizations during the week before illness onset. On interview, the first five cases reported shopping at the same grocery store (retailer A), which had a customer shopper-card program. All five cases had consumed fresh blueberries, in the week before illness onset four reported frequent fresh blueberry consumption, and three specifically reported consuming fresh blueberries purchased in 1 pint (16 oz.) clamshell containers from retailer A.

These 5 cases and 20 controls were enrolled in the case-control study. Consuming fresh blueberries was statistically associated with illness (5 of 5 cases vs. 8 of 19 controls; matched odds ratio [mOR], undefined; p=0.02). Consuming fresh blueberries from retailer A was also statistically associated with

illness (3 of 3 cases vs. 3 of 18 controls; mOR, undefined, p=0.03). None of the other 12 food items on the questionnaire were statistically significantly associated with illness.

On August 17, a sixth case was identified by MDH through routine surveillance. This case, also a female over 50 years of age, resided in a town located 50 miles from the small city where the first five cases resided. This new case also reported consuming fresh blueberries prior to illness onset. She reported purchasing blueberries in 1-pint clamshell containers from a different grocery store (retailer B) than the other five cases; retailer B did not have a shopper-card program.

All six cases were female, with a median age of 66 years (54 to 82 years). Illness onset dates ranged from July 17 to August 4, 2010 (Figure 4.2). One case was hospitalized for 4 days.

Traceback Investigation

On August 9, shopper-card reports confirmed blueberry purchases from retailer A for three of the cases prior to illness onset. Case 1 purchased 2 pints of blueberries on July 14, Case 2 purchased 2 pints of blueberries on July 13, and Case 3 purchased 12 pints of blueberries on July 14 (Table 4.1). No shopper-card information was available from Case 4 because the case did not use a shopper-card for purchases prior to illness onset. Case 5 was unable to be interviewed directly about shopper card information due to the severity of her

illness. Invoices collected from retailer A showed blueberries received from two suppliers in July prior to the start of illnesses: wholesaler A and wholesaler B.

In a telephone conversation with MDA, the manager of retailer A stated that blueberries sold on July 13 and July 14 would likely have come from incoming invoices dated July 10, 12, and 13. The invoice dates were the same as the shipping dates, and product from the July 10, July 12, and July 13 suppliers was shipped and received the same day (Figure 4.2). Records showed the last shipment of blueberries prior to July 10 was on July 3. As of August 16, before Case 6 had been identified, the information provided by retailer A led to a presumed link to a blueberry grower in Michigan (grower A) (Figure 4.2).

Table 4.1. Shopper-card numbers for three human cases of illness associated with fresh blueberry purchases between July 11 and July 17, 2010 from retailer A. All three cases purchased GTIN (UPC) AAAAA600111.

Human Cases	GTIN (UPC)	Description	Visits	Quantity Sold
Case 1	AAAAAA600111	Berries – Blueberries	1	2
Case 2	AAAAAA600111	Berries – Blueberries	1	2
Case 3	BBBBBB900690	Berries – Blueberries	1	3
	AAAAAA600111	Berries – Blueberries	1	9

An inspection at retailer A found no reported employee illness in the timeframe prior to the cases' illnesses. The inspector verified that blueberries were never repacked at the store prior to sale. An assessment of the walk-in produce storage cooler, retail display cooler, and produce processing area was conducted, and no issues were observed.

On August 20, Case 6 provided a receipt documenting a purchase of fresh blueberries from retailer B on July 15, and retailer B was contacted by MDA and provided invoices for blueberries received between July 1 and July 15, 2012. All blueberries had been provided by a single wholesaler (wholesaler C) and a single grower (grower B) (Figure 4.2). At this point in the investigation, a common source of blueberries for Case 6 and the previous cases was not evident (Figure 4.2).

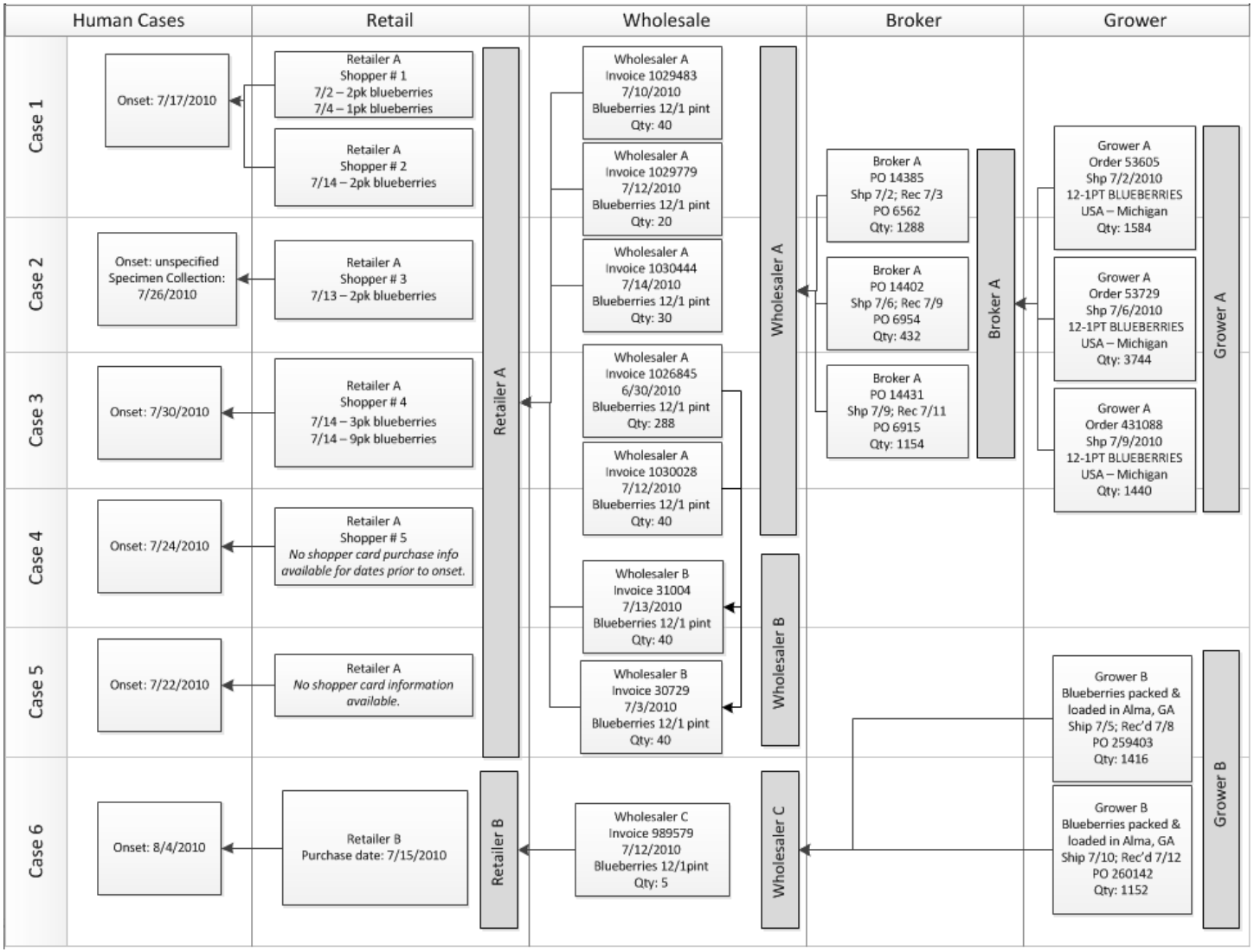
On August 20, MDA received Point-of-Sale (POS) GTIN information for all blueberries sold at retailer A from July 11 to July 17 associated with all available case shopper-card purchase data. In addition, retailer A provided a count of the units sold by GTIN for July 13 and July 14, the dates when the three cases with shopper-card information purchased blueberries (Table 4.2).

Table 4.2. Total units of fresh blueberries (16 oz.) sold by retailer A on July 13 and July 14, 2010. GTIN (UPC) AAAAAA600111 were purchased by all three cases from whom shopper-card data were available.

	Fresh Blueberries (16 oz) Units Sold	
PLU and GTIN (UPC)	**July 13, 2010**	**July 14, 2010**
4240	0	54
XXXX322001	0	0
XXXX322101	15	0
BBBBBB900690	103	291
AAAAAA600111	433	378

The universal product code (UPC) barcode on the blueberry clamshell packages encoded a 12 digit number (GTIN-12) unique to each brand and product combination, which allowed it to be scanned and recorded at checkout and associated with individual shopper-card numbers. At the time of inquiry, retailer A had 17 UPCs recorded in their system for blueberries. All three cases for which shopper-card information was available had one common GTIN: AAAAAA600111 (Table 1). Using the GTIN GS1 barcode look-up database, this UPC was found to be associated with grower B located in Alma, Georgia. Importantly, this UPC POS information was inconsistent with the invoice information collected from retailer A since the provided invoices did not identify any shipments that traced back to grower B. In other words, grower B did not match any of the suppliers of blueberries for retailer A identified by the traditional traceback methods of reviewing invoices, bills-of-lading and product handling practices (Figure 4.2).

Figure 4.2. Traceback diagram created initially in the investigation based on first-in-first-out product rotation and traditional traceback methods of analyzing invoice, bill-of-lading, and product handling practices. Based on this information, a common source of blueberries for all cases could not be identified.


Human Cases
Retail
Wholesale
Broker
Grower
Case 1
Case 2
Case 3
Case 4
Case 5
Case 6
Onset: 7/17/2010
Onset: unspecified
Specimen Collection:
7/26/2010
Onset: 7/30/2010
Onset: 7/24/2010
Onset: 7/22/2010
Onset: 8/4/2010
Retailer A
Shopper # 1
7/2 – 2pk blueberries
7/4 – 1pk blueberries
Retailer A
Shopper # 2
7/14 – 2pk blueberries
Retailer A
Shopper # 3
7/13 – 2pk blueberries
Retailer A
Shopper # 4
7/14 – 3pk blueberries
7/14 – 9pk blueberries
Retailer A
Shopper # 5
No shopper card purchase info available for dates prior to onset.
Retailer A
No shopper card information available.
Retailer B
Purchase date: 7/15/2010
Retailer A
Retailer B
Wholesaler A
Invoice 1029483
7/10/2010
Blueberries 12/1 pint
Qty: 40
Wholesaler A
Invoice 1029779
7/12/2010
Blueberries 12/1 pint
Qty: 20
Wholesaler A
Invoice 1030444
7/14/2010
Blueberries 12/1 pint
Qty: 30
Wholesaler A
Invoice 1026845
6/30/2010
Blueberries 12/1 pint
Qty: 288
Wholesaler A
Invoice 1030028
7/12/2010
Blueberries 12/1 pint
Qty: 40
Wholesaler B
Invoice 31004
7/13/2010
Blueberries 12/1 pint
Qty: 40
Wholesaler B
Invoice 30729
7/3/2010
Blueberries 12/1 pint
Qty: 40
Wholesaler C
Invoice 989579
7/12/2010
Blueberries 12/1pint
Qty: 5
Wholesaler A
Wholesaler B
Wholesaler C
Broker A
PO 14385
Shp 7/2; Rec 7/3
PO 6562
Qty: 1288
Broker A
PO 14402
Shp 7/6; Rec 7/9
PO 6954
Qty: 432
Broker A
PO 14431
Shp 7/9; Rec 7/11
PO 6915
Qty: 1154
Broker A
Grower A
Order 53605
Shp 7/2/2010
12-1PT BLUEBERRIES
USA – Michigan
Qty: 1584
Grower A
Order 53729
Shp 7/6/2010
12-1PT BLUEBERRIES
USA – Michigan
Qty: 3744
Grower A
Order 431088
Shp 7/9/2010
12-1PT BLUEBERRIES
USA – Michigan
Qty: 1440
Grower A
Grower B
Blueberries packed & loaded in Alma, GA
Ship 7/5; Rec'd 7/8
PO 259403
Qty: 1416
Grower B
Blueberries packed & loaded in Alma, GA
Ship 7/10; Rec'd 7/12
PO 260142
Qty: 1152
Grower B

On August 26, MDA received POS GTIN information from retailer B, the store where Case 6 had a receipt confirming the purchase of blueberries on July 15. The GTINs for all fresh blueberries sold on July 15 at Retailer B matched the GTIN for cases 1, 2, and 3 associated with retailer A: AAAAAA600111. This GTIN was the only GTIN sold at retailer B on July 15 (Figure 4.3). Therefore, GTIN and traditional traceback records collected from retailer B were in agreement, and both sources of information implicated grower B.

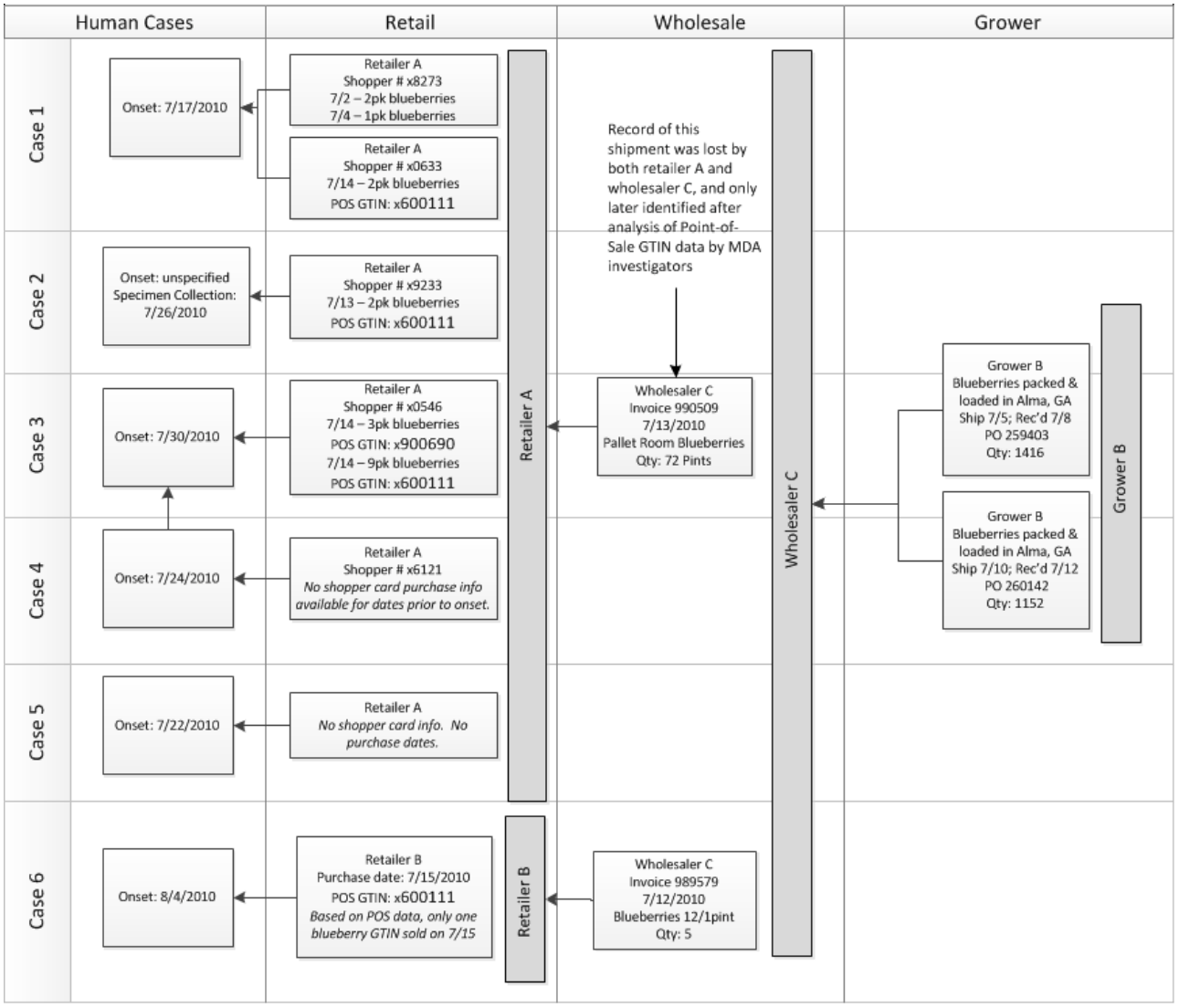
Figure 4.3. Point-of-sale GTIN information from retailer B for sales of fresh blueberries (16 oz.) from July 11 through July 17, 2010. Case 6 provided a receipt from retailer B showing a purchase date of July 15, 2010. Only GTIN AAAAAA600111 was sold on July 15 and this GTIN matched the shopper-card purchase information from three cases who shopped at retailer A.

Description		7/11 Sun	7/12 Mon	7/13 Tue	7/14 Wed	7/15 Thu	7/16 Fri	7/17 Sat	Unit Sold	Sales
10300 BLUEBERRIES PINT										
[redacted] 922201 FRESH BLUEBERRIES PINT 1			1						1	$1.99
[redacted] 322001 FRESH BLUEBERRIES 1								8	8	$15.92
[redacted] 322101 GREAT SUNBELT BLUEBERRIES 1		15	26						41	$96.59
[redacted] 005040 FRESH BLUEBERRIES PINT 1			19	38	1			3	61	$121.39
[redacted] 600111 FRESH BLUEBERRIES PINT 1				9	49	53	40	27	178	$354.22
	Total :	**15**	**46**	**47**	**50**	**53**	**40**	**38**	**289**	**$590.11**

On September 3, MDA investigators contacted grower B to request information on fresh blueberry shipments to wholesaler C on or prior to July 15. On September 15, MDA investigators contacted wholesaler C to request all records showing shipments of fresh blueberries to retailer A on or prior to July 15. MDA received verbal indication that they had sold no blueberries to retailer A during that timeframe. However, because the GTIN information from retailer A did indicate that grower B blueberries had been sold at retailer A, and wholesaler A was known to have received grower B blueberries, MDA sent an inspector to retailer A on September 17 to look for missing invoice information. During that visit the inspector hand reviewed all invoices in the facility and found an invoice from wholesaler C indicating that they had supplied retailer A with fresh blueberries on July 13. After sharing this invoice with wholesaler C, who had previously denied shipment to retailer A, the matching records for the July 13 shipment were located and confirmed by wholesaler C and sent to MDA (Figure 4.4). The missing invoice was located in the files of retailer A but had been missed by employees at both retailer A and wholesaler C after phone and e-mail requests for records. Only the on-site visit by the MDA inspector and a thorough review of all records produced the missing invoice.

Grower B shipped blueberries to Minnesota twice, on July 5 and July 10 (Figure 4.4). Both shipments originated in Alma, Georgia. Therefore, the GTIN information collected from retailers A and B definitively identified grower B.

Figure 4.4. Modified traceback diagram created after shopper-card and point-of-sale GTIN information identified a single blueberry grower common to a majority of the human cases. Based on this information, investigators identified grower B as the likely source of the outbreak.


Human Cases
Retail
Wholesale
Grower
Case 1
Case 2
Case 3
Case 4
Case 5
Case 6
Onset: 7/17/2010
Retailer A
Shopper # x8273
7/2 – 2pk blueberries
7/4 – 1pk blueberries
Retailer A
Shopper # x0633
7/14 – 2pk blueberries
POS GTIN: x600111
Record of this shipment was lost by both retailer A and wholesaler C, and only later identified after analysis of Point-of-Sale GTIN data by MDA investigators
Onset: unspecified
Specimen Collection: 7/26/2010
Retailer A
Shopper # x9233
7/13 – 2pk blueberries
POS GTIN: x600111
Onset: 7/30/2010
Retailer A
Shopper # x0546
7/14 – 3pk blueberries
POS GTIN: x900690
7/14 – 9pk blueberries
POS GTIN: x600111
Wholesaler C
Invoice 990509
7/13/2010
Pallet Room Blueberries
Qty: 72 Pints
Grower B
Blueberries packed & loaded in Alma, GA
Ship 7/5; Rec'd 7/8
PO 259403
Qty: 1416
Grower B
Blueberries packed & loaded in Alma, GA
Ship 7/10; Rec'd 7/12
PO 260142
Qty: 1152
Grower B
Onset: 7/24/2010
Retailer A
Shopper # x6121
No shopper card purchase info available for dates prior to onset.
Onset: 7/22/2010
Retailer A
No shopper card info. No purchase dates.
Retailer A
Wholesaler C
Onset: 8/4/2010
Retailer B
Purchase date: 7/15/2010
POS GTIN: x600111
Based on POS data, only one blueberry GTIN sold on 7/15
Retailer B
Wholesaler C
Invoice 989579
7/12/2010
Blueberries 12/1pint
Qty: 5

MDA investigators notified the FDA Minneapolis District Office of their traceback investigation. Since no new cases were detected in Minnesota and due to the limited shelf life and growing season of the implicated blueberry product, no formal recall was requested of grower B. No cases in other states were linked to blueberry consumption.

Discussion

This was an outbreak of *Salmonella* Newport infections associated with consumption of fresh blueberries. We could find reference to only one previous outbreak of salmonellosis associated with blueberries – a multistate outbreak of 14 *Salmonella* Muenchen cases in 2009 reported in the CDC Foodborne Outbreak Online Database (73).Because case numbers in our outbreak were small, and because blueberries were not a well-documented vehicle of salmonellosis, it was important to corroborate the statistical association found in the case-control study by determining that the blueberries consumed by cases originated from a common source. The methods used to detect and investigate this cluster, including the traceback methods, once again proved very effective in determining a novel vehicle of foodborne disease even with relatively few cases in the outbreak (16,45). However, methods used to rapidly trace back suspected food products as part of an epidemiologic investigation are evolving (15), and valuable lessons about this process were learned during this investigation.

In many outbreak investigations, exact purchase dates are difficult to obtain or verify. The use of shopper-card data by investigators helps narrow the focus of the investigation to specific purchase dates and can be used to link customer purchases to incoming shipments to the retailer. Since these data are queried from databases, they tend to represent a more reliable measure of temporal exposure when compared with case recall during a phone interview. In the absence of shopper-card data, product that cases were most likely exposed to is typically determined by first-in-first-out (FIFO), an inventory method designating that the oldest product on the shelves should be sold first. There is often minimal documentation of whether a firm is accurately and consistently following FIFO, and therefore an investigator's links between the dates a product is sold and the incoming invoices are frequently based on employees' assumptions of throughput and sales. Based on initially incomplete evidence in this investigation, the invoices pointed to wholesaler A and grower A based on FIFO. However, when point-of-sale (POS) data were analyzed and linked to shopper-card information, a common GTIN was identified. This finding revealed the likelihood that not all invoices had been provided by retailer A in the initial data request, and led to additional investigation both at retailer A and wholesaler C. The discovery of additional records at these locations documented the supply chain from grower B to wholesaler C to retailer A, thereby shifting the focus of the investigation from grower A to grower B. The current reliance on a paper-based on-up/one-back system of traceability between trading partners demonstrates

real world data gaps since both retailer A and wholesaler C had inadvertently failed to provide records that would have immediately implicated grower B.

Blueberries are somewhat unique compared to other fresh produce products since they are not usually repackaged or sold in bulk at retail, but are sold in clamshell packages that have a UPC barcode. Because product from several blueberry growers can be available for sale in a single retail setting within a short timeframe, this presents an opportunity to use shopper card, GTIN and POS information in an investigation. This situation allows investigators more opportunity to find a common lot code or GTIN associated with illness. Other packaged fresh produce products such as sprouts, raspberries, blackberries, and strawberries may have similar sales characteristics. The unique GTINs allowed investigators to differentiate between individual purchases as well as see, in aggregate, which GTINs were sold on a particular day. Of note, once a common GTIN had been identified, determining the brand owner for that GTIN required additional analysis by MDA investigators since the company that originally registered the GTIN had since merged with another entity.

This investigation demonstrates the emerging concepts of Critical Tracking Events (CTEs) and Key Data Elements (KDE) (37) related for food product tracing. These concepts could be critical in rapidly tracing food though the supply chain and solving outbreaks. The POS data, essentially a CTE, represents

transactional event data that associates the sale of a product to an individual at a point in time. Simply put, this shopper-card CTE identifies “who” purchased “what” and “when”. In this traceback investigation, GTINs, shopper-card numbers, dates and times represent the KDEs needed to link a product to a case of illness. It should be noted that all the data accessed by regulators in this investigation were originally created for business purposes (sales information, marketing, etc.) and not originally intended by industry to be used for traceability. However, the use of these data and the event data that were queried by investigators demonstrates the potential utility of consciously designed CTEs and KDEs at critical points in the supply chain to better facilitate product tracing.

Also, because the blueberries were packaged and marked with their GTIN information on the consumer packaging and because this GTIN information was recorded at the POS, investigators were able to query the trade-item ownership using a public online database. Under different circumstances, even if invoice information from retailer A and wholesaler C had not been missing, this information could still have allowed investigators to bypass steps in the supply chain and identify the source more quickly.

The passage of the Food Safety Modernization Act requires most entities in the supply chain to maintain better traceability records for high-risk foods, and this outbreak demonstrates the ability of investigators to use these data to more

effectively identify the source of an outbreak. This outbreak suggests that even modest improvements in food traceability can be made by businesses properly defining CTEs and capturing KDEs. The use of CTEs and KDEs would greatly improve the speed and accuracy of outbreak and traceback investigations.

In conclusion, this outbreak investigation involved only six cases and only two retailer locations, but this proved sufficient to conclusively identify the source as blueberries and link all the exposed cases to a common grower. The investigational efficiencies gained by incorporating product tracing as part of an epidemiological investigation cannot be understated. Many larger multistate outbreaks could be solved more quickly if coordinated and concentrated product tracing was routinely conducted by public health and regulatory agencies in states with even a few cases (4,6). In this instance, the use of POS UPC and GTIN information was a critical component of the traceback investigation. This type of information represents a rapid, specific source of data and should be routinely sought and incorporated into food traceback investigations. The food industry should also consider points in their processes where CTEs could be implemented to better facilitate product tracing.

Because fresh produce items are highly perishable, some may question the importance of finding the source of the issue, given that by the time this occurs the outbreak is generally over and therefore there is no immediate public health

impact. However, successfully tracing an implicated product to its source allows regulatory and public health officials to conduct a root cause analysis or environmental assessment to determine how the product may have initially become contaminated and prevent future contamination events.

Chapter 5. Summary

This first paper presented in this dissertation proposed the need and subsequent structure for improved traceability in the food supply chain by employing the concept of Critical Tracking Events (CTEs); specifically Terminal, Aggregation/Disaggregation, Transfer and Comingling CTEs. This paper develops a conceptual framework needed to improve the timeliness and accuracy of data collected throughout the food supply modeled after a similar approach used in the development of Hazard Analysis and Critical Control Points (HACCP). Through the systematic use of Critical Tracking Events, food operators are able to analyze their individual processes and identify points to collect "what, where, and when" data and create a Unique Traceability Code that can serve as a unique data identifier throughout the supply chain. This system would allow public health investigators to use distributed databases and cloud based computing systems to rapidly query the food distribution system looking for spatial and temporal commonalities for suspected food items in an outbreak. The primary benefit of implementation of CTEs to the food industry is not to immediately improve food safety but to increase operational efficiency. However, by implementing appropriate CTEs throughout the supply chain, public health investigators and regulators can use this information to quickly find points of convergence of products implicated in an outbreak and make an intervention, which prevents additional illnesses from occurring. The development of this type of product tracing system is mandated by the Food Safety Modernization Act and

is designed to build on data and recommendations stemming from pilot studies involving produce and processed manufactured foods.

The second paper in this dissertation documented the first known cases of *E.coli* O157:H7 associated with a nut product while also proposing methods for the type of records and information that should be collected as part of a traceback investigation used to rapidly test an epidemiological hypothesis. In this outbreak, seven retail food locations, six (86%) in Minnesota and one (14%) in Wisconsin received suspect hazelnut or mixed-nut (containing hazelnuts) shipments from a distributor in Minnesota and Wisconsin, respectively. Records were collected from retail and distribution facilities in Minnesota, Wisconsin and Michigan, and traced back to a single distribution center in California. Because of comingling practices at the distribution center in California and the lack of Critical Tracking Events to capture Aggregation/Disaggregation or Comingling CTEs the firm was required to initiate a product recall. The majority of hazelnuts received at the California distributor came from a packing operation in Oregon. This packing operation, due to process and recordkeeping gaps, also lacked CTEs that would have allowed for the identification of a suspect farm or group of farms. This investigation demonstrated how regulatory and public health investigators used well defined epidemiological and traceback methods to trace suspect products back through the supply chain. The investigation also demonstrated how a lack of CTEs and the corresponding “what, where, and when” information prevented

investigators from determining the ultimate source, likely a farm, in this outbreak. Had the source farm been identified, an environmental assessment may have identified the root cause of contamination and provided guidance to the hazelnut industry on how to prevent *E.coli* O157:H7 contamination in the future.

The third paper describes an outbreak of *S.* Newport associated with blueberries involving the novel use by investigators of Global Trade Item Numbers in the form of Universal Product Codes to identify the source grower for the outbreak. Six cases of confirmed illness, all occurring in Minnesota, purchased blueberries from two retail locations. Early in the investigation regulators use "traditional" sources of data to attempt a traceback; invoices, bills-of-lading, and shopper receipts. Shopper-card information and point-of-sale transaction data queried from the retailers' data systems allowed investigators to identify a supplier-specific 12-digit GTIN that was linked to case purchases and corroborate the results of case-control study in which fresh blueberry consumption was statistically associated with illness (5 of 5 cases versus 8 of 19 controls, matched odds ratio [MOR] undefined, $P = 0.02$). In this investigation the shopper-card information represented a CTE at the retail store because it identified "what" (GTIN) product was sold to "whom" (shopper-card number) and "where and when" (retail location and date and time of sale) this transaction occurred. This investigation demonstrates how investigators can determine the source of an outbreak can use CTEs, and a limited set of transaction data, KDEs.

In conclusion, food traceability is complicated and inconsistent throughout the food supply chain because of existing business processes, cost and the lack of regulatory requirements for collecting these data. Several nationwide outbreaks in the 2000s resulted in the passage of the Food Safety Modernization Act which required the FDA to create a product tracing system and the food industry to collect more information to better facilitate traceability.

The primary objective of this research is to characterize and propose how data could be more systematically defined and collected throughout the food supply chain to more rapidly determine the source of foodborne illness outbreaks. Building on the concepts that the food industry has used implementing HACCP plans, this dissertation proposes a similar structure that can be used to identify and create CTEs that capture a small amount of "what, where and when" data in a format convenient to the food operator. Additionally, the regulatory and public health communities can improve current traceback investigations by more methodically collecting data and food handling practice information from existing data sources. Finally, if investigators and public health officials approach a traceback investigation looking for possible undefined CTEs in the supply chain, they may identify unique or novel opportunities for analyzing data sources not previously considered.

It will take a significant period of time for the food industry to adopt and implement the concepts of CTEs throughout the supply chain and even longer before regulatory officials have a centralize search tool to query these data. In the meantime, investigators can used the methods and concepts described in this dissertation to solve traceback investigations more quickly and potentially limit the number of illnesses in a some foodborne outbreaks.

Future Research

As the CTE concept gains acceptance in the food industry additional research demonstrating how the CTE can be implemented would be useful. This research could involve a combination of the development of “Pilot Plants” as well as discrete event simulation to create computer models that demonstrate how data are systematically collected using CTEs and how Unique ID codes can be shared within companies and between food operators.

Pilot Plants are used in the food industry to test new processes and products and this concept could be extended to testing CTE data collection within a variety of food operations; produce packing sheds, warehouses, and food manufacturers. These small-scale plants could mirror larger processes in the real-world and demonstrate how operators may systematically collect data at predetermined CTEs with the goal of minimally impacting existing production processes.

Computer simulations of product supply chains, both within a processing facility and representing transactions and shipments between companies, could be developed using discrete event simulation software. Such software can create visual representations of the food supply can show where and how data can be most effectively collected to improve food traceability. These software can be tailored to almost any situation and could help food operators design a cost-effective and high-performance system with minimal impact on production practices or product throughput.

Building on the research described in this dissertation and with additional research, food traceability can be improved with the secondary benefit of protecting public health when outbreaks do occur. Rapidly tracing food products associated with illness to their sources can prevent additional illnesses for that outbreak and root cause analyses can prevent future illnesses.

Specific recommendations for improving food traceability include:

1. The food industry should analyze current processes and determine where to implement CTEs and collect a small amount of “what, where, and when” data – Key Data Elements – and develop methods to share these data between food operators in the supply chain.

2. Regulators should methodically collect data and information related to product tracing using currently available data sources. Standardization of these

investigatory methods, even in the absence of industry available CTEs, would reduce the time and increase the accuracy of traceback investigations.

3. Investigators should look for CTEs when conducting investigations by fully understanding an operator's product handling processes and what data are currently collected as part of these processes. This understanding by the investigator may allow for the identification of novel or nontraditional data sources to be used in a traceback investigation.

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