



## Introduction

In the U.S., foodborne illness accounts for approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually (Mead et al. 1999). Based upon the USDA Economic Research Service (ERS) and Centers for Disease Control (CDC) estimates of incidence, outcome severity, and medical, productivity, and disutility costs, outbreaks of Salmonella and E. coli O157:H7 alone are estimated to cost the U.S. \$3,124,811,739 annually (USDA 2009b).

While there are more than 200 known diseases transmitted through food, a primary complicating factor in detecting foodborne illness is that many pathogens or agents are not readily identifiable or diagnosable. The CDC estimates that more than 75% of illnesses, hospitalizations, and deaths are caused by unknown agents and pathogens. Some of the most recognizable pathogens today (e.g., E. coli O157:H7) were not recognized as the cause of foodborne illness until the last twenty years (Mead et al. 1999). Considering the degree of difficulty in identifying certain strands of illness through simple testing (since so many illnesses, hospitalizations and deaths are attributed to unknown agents), it is imperative that other means be developed to narrow the investigative process and more quickly locate the source of an outbreak. An effective traceability program would go a long way toward making our food safety system safer.

A foodborne illness outbreak is defined as two or more cases of a similar illness resulting from ingestion of a common food (Mead et al. 1999). Advances in technology have made the detection of foodborne illness and foodborne illness outbreaks more rapid. One such technology is PulseNet, a system utilized by the CDC. PulseNet, which uses standardized protocols, software, and nomenclature, was created after a major E. coli O157:H7 outbreak in 1993 that caused approximately 800 illnesses. In the 1993 E. coli outbreak, scientists used DNA “fingerprinting” to match the strain of E. coli found in sick patients with a strain found in hamburger patties that were served by a fast food chain. Investigators realized that had they been able to more rapidly identify the DNA match they would likely have been able to prevent many of the illnesses that occurred. PulseNet was designed as an on-demand electronic database of DNA “fingerprints” of disease-causing bacteria taken in a standardized manner from both sick humans and food suspected of being infected. The CDC conducts searches of the database in order to identify clusters of illnesses with the same DNA footprint. This rapid electronic detection of DNA “fingerprint” clusters across the U.S. enables the CDC to distinguish and react to outbreaks far more rapidly than was previously possible; outbreaks that once took days to discover can now be detected in hours (National Center for Infectious Diseases 2009).

While technological and communication advances, such as PulseNet, have aided in the *detection* of outbreaks, there is still considerable difficulty in investigating and tracing foodborne illness outbreaks back to the *source* of the problem. A recent study by the Alliance for Food & Farming illustrates the importance of being able to identify the source of a foodborne illness outbreak (Alliance for Food & Farming 2010). In those investigations in which there was a successful source implication, only 2% of outbreaks and 6% of illnesses were confirmed as problems associated with growing, packing, shipping, or processing fresh produce. According to the same study, 65% of the illness outbreaks associated with produce were attributed to restaurant mishandling, 14% to mishandling at community events, and 13% to mishandling in the home. These data are based upon confirmed cases, and do not account for those outbreaks and illnesses in

which a source was never implicated. Because the source of a contamination dictates the response (contamination from mishandling produce at a community event would be handled very differently from contamination originating at the grower level) it is extremely important to be able to trace a foodborne illness outbreak back to its source.

Once the source of contamination and the scope of products affected are identified, the FDA attempts to trace forward to each location in which the product was shipped in order to facilitate a recall. Any recordkeeping lapse can cause delays in this process, thereby extending the ultimate removal of other contaminated product from commerce.

As the U.S. population becomes more urban and more removed from any direct link to the food supply, consumer confidence in the safety of the food supply is critical. Despite an increase in government oversight and significant advances in the detection and investigation of foodborne illnesses and outbreaks, the number and severity of incidents has not decreased in recent years. In 2009, the Produce Traceability Initiative (PTI) was proposed by a coalition of fresh produce industry leaders as a voluntary industry effort to “enhance total supply chain traceability to better serve our customers, to expedite tracebacks and recalls, and more narrowly isolate potential recalls or other problems when they do occur,” (PMA 2009a; PMA 2009b; PMA 2009c). The PTI was developed to help establish a common system of traceability across commodities in the produce industry.

Although it was proposed by industry leaders, industry support for the PTI is mixed at best. The cost of implementation has been a major hurdle for both suppliers and distributors of fresh produce due to the additional technological and labor expenses involved in adding a lot-specific barcode to each box and then reading and storing that data. Additionally, the use of a highly standardized approach to labeling a wide variety of commodities with different growing, packing, and handling processes creates additional burdens for users. For those firms that are already complying with one-up, one-down regulations under the U.S. Bioterrorism Act, doubt exists that the addition of a “barcode on a case” will be helpful to a traceback investigation performed by the FDA. Finally, critics are worried that the PTI makes it easier for regulators to use the grower as a scapegoat by providing a simpler mechanism to point straight back to the point of origin instead of the path through which food traveled on its way to consumers.

Proponents of the PTI cite the differences between *process* flow (the physical flow of the product through the supply chain) and *transactional* flow (the flow of money and paperwork in the sales and distribution through the supply chain) as a major benefit of the PTI. A more robust tracing system that identifies each physical location (the process flow) through which produce is handled instead of only transactional data (such as invoices) could shorten the time-consuming process required to trace the physical path of produce through the supply chain. The electronic footprint left by the PTI can provide a standardized link between each point in the supply chain through which the product moves and, subsequently, might be contaminated. As the flow of money and sales is very often different than the flow of physical produce, authorities will be able narrow the number of commodities, brands, and companies implicated in an outbreak by matching outbreak locations to specific lots of product sold through those locations. Accordingly, labels identifying the brand owner, commodity, product identification, and lot would not be used simply to identify the original supplier but rather to identify all relevant handlers along the supply chain.

## **Objectives**

This research has three primary objectives:

1. Establish future goals for an ideal fresh produce traceability system;
2. Assess the extent to which the PTI meets the goals of an ideal fresh produce traceability system as well as the stated goal of enhancing the supply chain by expediting tracebacks and recalls, and more narrowly isolating potential recalls or other problems when they occur; and
3. Develop a set of recommendations or principles to guide future traceability systems.

## **Procedures**

Our first objective was to develop a set of future goals for an effective traceability system. To that end, we started with a thorough review of existing local, state, and federal regulatory requirements to develop a complete picture of the current chain-wide traceability system as it applies to produce, as well as its strengths and shortcomings. Primary research was then conducted in the form of open-ended interviews with growers, shippers, brokers, retailers, foodservice providers, and distributors in the fresh produce supply chain. The objective of the interviews was to determine the strengths and shortcomings of the current system in order to formulate a set of future goals for a successful traceability system. This primary research was supplemented with publicly available comments and information from presentations by major firms in the produce supply chain. A total of 17 interviews were conducted with representatives of grower/shippers, brokers, processors, retail chains, technology vendors, and industry associations using an interview guide. The majority of these interviews were carried out in-person; a few interviews were conducted by telephone. Secondary research was then analyzed, focusing on the strengths and shortcomings of the existing system. The analysis was based on previous academic work in the field, government documents, public testimony of supply chain participants before Congress, the FDA, the CDC, the USDA, legislation, and documentation from various electronic sources regarding specific initiative data. We also examined two case studies for a deeper understanding of the food safety system, the 2006 E. coli contamination of fresh spinach and the 2008 salmonella contamination of peanut butter.

Second, we develop a set of future goals that would improve upon the effectiveness and timeliness of the current traceback system. A four stage iterative process was employed such that these goals encompassed, as accurately as possible, data accumulated through interviews as well as the analysis of secondary research. The first stage was to lay out each “shortcoming” in the current system as illustrated by primary and secondary research (interviews with supply chain members, FDA testimony and public releases, and an analysis of recent major outbreak and recall shortcomings). The second stage was to examine the shortcomings identified through various methods, looking for similarities such that they could be grouped into more cohesive categories. The third stage was to turn each category of “shortcomings” on its head and to develop “goals” for an effective traceability system. Finally, we compared the future goals to the original shortcomings from stage one to ensure that the synthesized final goals did not lose their original substance. This process was then repeated until the substance of the original shortcomings and the substance of the synthesized goals were one and the same.

The third step was to assess the PTI relative to the future goals. We laid out the PTI in detail and compared the system that the PTI would create in the supply chain to that of the future goals. This analysis allowed us to highlight what the PTI accomplishes conceptually and where it falls short. It is important to note that the PTI is described as a “living document” which is regularly updated. In order to maintain a consistent analysis, a single version of the PTI documentation as of May, 2010 was utilized.

Finally, based on the above analysis of the future traceability goals and the assessment of the PTI, we develop recommendations or principles that should be adopted in order to help ensure that future versions of the PTI will result in an effective, timely, and accurate traceability system for the produce industry.

## **Traceability Future Goal Development and PTI Assessment**

In the following analysis we develop five future goals for a successful traceback system. We then use these goals as a means to assess the PTI’s potential to increase the speed and accuracy of traceback and recall events.

### *Goal I. Standardization of Datasets*

The FDA has indicated that a lack of uniqueness (or existence) of lot or code information makes any trace-back much wider in scope and therefore more complicated and time-consuming than would be the case with a unique lot identifier (USDA 2009a). The level of detail that should be captured is the primary issue. As evidenced through grower/shipper interviews discussing a wide variety of commodities, the growing, harvesting, handling, processing and distribution of each unique commodity can vary so dramatically, that there is no single level of detail (e.g. by field or by day) that most accurately and efficiently fits each process and accomplishes the goal at hand. To this end, interview data were used to examine the level of specificity that would allow the narrowest possible recall in which all possible contaminated products could be effectively identified. The ideal level of detail would minimize financial damage incurred throughout the supply chain and that provide the breadth necessary to remove all potential contaminated product from commerce. Determining this level of uniqueness in identification comes down to two primary categories of information: common nomenclature and common level of detail. Goal I is therefore broken down into two sub-goals reflecting these two categories. The first category, common nomenclature, is further broken into three sub-categories, company identification, discernable product characteristics, and lot or batch information.

#### *Goal I.a. Common Nomenclature - Description*

The application and use of a common language for fresh produce is necessary such that each member of the supply chain has a shared understanding of a traceability “language.” The Harvard Business Tomato study concludes that the lack of consistency in the data presented causes major delays in rapidly following product through the supply chain (McEntire et al. 2009). Use of such a common nomenclature to describe individual products is essential to performing a rapid trace-back if technology is to be employed to be used with more rapid data mining techniques. A technology vendor put it most succinctly, indicating that when dealing with this nomenclature,

the specific means of delivery are irrelevant. Put another way, the utilization of a common technology or method of transfer across the supply chain is more important than the choice of the technology or method.

The choice of a common nomenclature is analogous in many ways to the use of different languages. If one member in the supply chain only speaks English, another only speaks Spanish and a third speaks only Chinese, then rapid communication is virtually impossible without the extensive use of a third party translator. It is imperative that any traceability nomenclature be uniform and consistently applied across the supply chain so that each member of the supply chain is able to read and understand the information. This nomenclature should be universal and allow for uniqueness on an international scale (especially considering the high degree of fresh produce imports into the U.S. food supply). This will allow the FDA to skip the step of “interpretation” from multiple “languages” and instead focus upon commonalities in source implication.

Interviews revealed that perhaps the most important part of a traceability system in terms of speed and accuracy is providing regulators with enough information such that they know both the right questions to ask as well as the right people to contact. A thorough analysis of our interviews and research on the current traceability process, indicate that there are three key components in to the nomenclature: unique company identification, discernable product characteristics, and lot or batch information. These are discussed below as Goals I.a.1., I.a.2., and I.a.3.

#### *Goal I.a. Common Nomenclature - Assessment*

The PTI directly addresses the concept of unique identifiers by utilizing the GS1 standard and the GS1 coding methodology as a means of creating a common nomenclature that is both universally recognized and unique in nature.

On a macro level, GS1 is an internationally recognized organization of common standards that provides a platform for unique codes. Standards for the individual codes that make up the PTI data scheme are all recommended based upon standards that are already in place and being used for other commercial purposes internationally. As a selection for nomenclature, the use of existing GS1 standards ensures that each member of the supply chain is speaking the same language to the degree that individual data elements are presented and utilized in a uniform manner across the supply chain. The selection of a uniform body of codes ensures that from a visual perspective (i.e. looking at the codes) and a system perspective (i.e. storing and accessing the codes) the individual elements are universally understood as the same data elements and designed for uniqueness in identification. GS1 does, indeed, offer the type of consistent nomenclature that is necessary as well as standards for the best-use and application of that language.

#### *Goal I.a.1. Company Identification - Description*

The ability to identify companies and their physical locations in a uniform and, most importantly, unique, fashion is paramount in any traceability nomenclature. Issues in identifying which company handled the product or grew the product drastically limit the scope of the investigation. As one interviewee pointed out, following the current one-up, one-down paper trail (as dictated by

the U.S. Bioterrorism Act) sometimes means following the financial flow of products rather than the physical flow.

By way of interpretation, this means that knowing the unique physical locations through which the product travels allows analysis of commonalities among multiple implicated products. The outcome of a limited investigation means that the speed and ability to implicate a specific product (and simultaneously exclude others from implication) is limited only by the specificity of the products identified through consumer outlets. In an industry where private labels are packed by multiple companies, identification of the specific company from which the fruit originated as well as those facilities through which the product passes is necessary.

Additionally, this interpretation suggests that the use of a unique identifier for each company is an effective method of following the physical product through the supply chain (i.e. the physical path the product takes as opposed to the monetary path in which dollars flow through the supply chain). Standardizing datasets throughout the supply chain requires that each member of the supply chain that handles product be identified uniquely and tracked uniformly throughout the process. In this way, the immediate previous source of the product (the prior firm that physically handled the product) may be recorded as well as the immediate subsequent recipient (the subsequent firm that physically handles the product).

#### *Goal I.a.1. Company Identification – Assessment*

The use of the GS1 Company Prefix numbers as the recommended code methodology within which to store and transmit the common nomenclature allows for the creation and use of datasets that ensure uniqueness of the source firm from which the product originated. Furthermore, both shippers and growers who maintain their own brand and processors who reconfigure or change the product in some fashion are required to apply labels with their company prefix.

While the PTI adequately handles the issue of determining the immediate prior firm that modified the product, it does not call for standardization of company codes at other levels of the supply chain, including some levels of distribution, retail, etc. This presents a situation in which regulators are presented with uniform company information at the application level (i.e. the medium selected for application of the dataset) that indicates the immediate prior modifier of the information but does not provide them with consistent information with which to trace the product fully through the supply chain. In other words, they will receive uniformly applied company codes that specify an original grower/shipper or brand owner in some parts of the investigation while needing to use other forms of identification for distribution centers, storage facilities and other locations that the product may pass through in other parts of the supply chain. This unevenly applied uniformity in the application of traceability presents a situation in which data reported are inconsistent and do not fully meet the goal of uniform company identification throughout the supply chain. By not utilizing a standard for each “stop” along the path of produce through the supply chain, investigations must rely upon multiple forms of information gathering in addition to the standardized data provided through the PTI. Utilization of standardized company codes across every member of the supply chain ensures that a dataset from one firm would indicate both the prior source and immediate destination and can be matched electronically with the datasets provided by the source company and destination company.

Additionally, the requirement that buyers with private labels utilize company prefixes as a standard part of the dataset (which indicates only the prior source of the product in which the product was modified or changed) does not accurately allow for the rapid traceability of physical product flow throughout the supply chain. Instead, regulators must first contact the buyer in order to even begin to identify the product. The PTI documentation on private labeling explains that the company prefix should be based upon the brand identified on the exterior of the box. Only if the exterior of the case is branded by the original grower or shipper (with private label packages inside the case) should the company prefix reflect the original source (PTI Steering Committee 2009). Again, it is important that company prefixes be used uniformly throughout the supply chain such that each firm that handles the product may be identified and that the combination of company and other unique data elements (product characteristics and lot/batch number) are able to be used uniformly nationwide. As many shippers who provide private label services for a buyer also either have a brand of their own (often sourced from the same lot) or provide private label services for multiple companies, the application of company codes is unnecessarily complicated in that it implicates multiple unique products, with different company or brand names, that all point back to the same original field.

As an example, following the goals established above, the dataset at each firm between a shipper, distributor, and retailer would include unique identifiers that show the flow of product from physical location to physical location. The shipper, distributor, and retailer's unique company codes are referenced, respectively, as the immediate prior and subsequent recipient of the product. The company identifier on each individual case identifies the last member of the supply chain to pack, reconfigure or process the product. Once reported correctly to investigators, the product flow can easily be determined because each unique location with each unique product creates a flow of product from location to location. As currently laid out in the PTI, this data flow is interrupted; the label indicates the brand owner (which, in the case of private labels is often a retailer and not a grower or processor) meaning further investigative work is required in many cases to trace back to the ultimate source. Additionally, because only brand owners are required to establish company identifiers, many links in the physical path of the product flow will not be identified without significant work tracing the product manually via documentation such as purchase orders, bills of lading, and invoices to determine each physical stop. As contamination may occur at locations in which the product physically passes through as opposed to locations in which it may simply be marketed (i.e. retail stores), identifying the brand owner doesn't necessarily assist in identifying possible contamination sources.

While the PTI does utilize a standardized company code, it does not use the company code uniformly across the supply chain. Company codes either represent the last organization to modify a package (as in a fresh-cut processor) or they do not (a private label owner that contracts the growing/packing/processing of products). Utilization of the same exact company code to indicate multiple physical points in the supply chain does not create a standardized data set. A standardized data set, when assembled with others across the supply chain in an investigation, should easily match the immediate prior handler with the immediate recipient. In other words, the dataset for the second location in a product's journey should indicate, in a uniform use of coding, that the first location was the immediate prior handler and vice versa. This would minimize or eliminate the need to fill in gaps for analysis of traceability data thus minimizing unnecessary and time-consuming extra steps in an investigation.

### *Goal I.a.2. Discernable Product Characteristics– Description*

Discernable characteristics allow each level of the supply chain, including the end consumer, to identify and distinguish any given product from any other. This detail can include commodity, variety, brand, packaging, and post-harvest processing (e.g. cut or bagged). The important point is not the level of detail as much as the commonality of detail and understanding across the supply chain and by the consumer. This level of detail may or may not be referred to by each member of the supply chain or on individual paperwork used throughout the supply chain (i.e. bills of lading or invoices). While not every member of the supply chain has access to a visual portrayal of products still available for consumption (i.e. product that is still on grocery shelves but is no longer in pipeline inventory), it is also the case that not every member of the supply chain has access to existing electronic data (i.e. consumers at home or grocery clerks in remote areas without constant access to electronic means of communication). By matching the electronic identifier with the visual identification that makes the product discernable from another, implicated fresh produce may be communicated throughout the supply chain as well as with consumers and regulatory bodies in a uniform manner. This means that what the consumer physically “sees” when making a purchase is what the code “says” when used by members of the supply chain.

### *Goal I.a.2. Discernable Product Characteristics– Assessment*

The PTI uses reference numbers to identify each of a company’s products. The reference number utilizes GS1’s product identification scheme for use in its standardized GTIN numbers. A GTIN, or Global Trade Item Number, is a standardized code devised by GS1 to globally identify any item that could be sold or appear on a price list (GS1 2009). In defining the methodology through which product reference numbers should be selected and identified, the PTI plan calls for product identification based upon the characteristics primarily used for selling. While this method makes sense from an e-commerce perspective, it is unclear how the standardization of primary product attributes based upon selling characteristics will directly enable trace-back investigations and recalls to occur in a more timely fashion. As shippers do have different selling processes (even with the same commodities, processes, and volumes), the identification of a product in a recall situation involves sifting through many product identification codes to interpret the range of codes that essentially mean the exact same thing. That is to say, regulators would again find themselves trying to connect the dots between unique points of data (disparate reference numbers) that all potentially mean the exact same thing in the context of a recall. While advanced analysis using analytics software can aid in this process, investigators must still ultimately take the time to determine whether or not one code is the equivalent of another. This added overhead and work required to tie things together is unnecessary for an accurate recall. For example, while two separate companies both ship bags of chopped romaine lettuce each will have a unique methodology for creating reference numbers and, thus, will have different reference numbers. While this differentiation is, to some degree, due to the nature of the differing methods by which individual companies buy and sell, some concrete methodology should be established such that multiple reference numbers don’t exist to identify the same identical product (as with a bag of chopped romaine lettuce). If the differentiation between the two reference numbers is, indeed, brand, this should be spelled out. The characteristics necessary for an effective trace-back to link

to what a consumer actually eats are the characteristics that need to be identified in a reference number.

The sheer quantity of potential unique reference numbers has caused a major problem. There is great disparity in the understanding and application of reference numbers among shippers. Shippers with a similar number of commodities, processes, and relative volumes had differences in the number of GTIN's utilized for their products as large as 1,000 reference numbers. One shipper specifies that the lowest level of detail required is the commodity while others engaged in the same business identify GTIN's based upon every possible combination of variables in the selling process. The level of detail specified for reference numbers as laid out in the PTI is clearly ambiguous to those members of the supply chain charged with the creation of the reference numbers. In our interviews, not a single set of shippers had the same philosophy for assigning GTIN's. While the voluntary nature of the PTI means that some growers and shippers may not follow its guidance, sufficient guidance has clearly not been provided to assist those charged with the responsibility for implementing the PTI. As evidenced in interviews, spoken nomenclature used to refer to products tended to be very similar while the assignment of reference codes applied to these same products tended to vary greatly.

From an implementation perspective, the uneven use of reference numbers will create an added cost and burden to each member of the supply chain. Any time any single member of the supply chain adds or modifies a reference number, each other member that may potentially touch that product would potentially need to be contacted with updated GTIN's so that their method of receiving and recording the dataset retains its integrity. The tools suggested by the PTI for synchronization of GTIN's between supply chain members will largely minimize the difficulty in the data exchange portion of implementation. However, the data synchronization tools provided cannot match product received with an individual shipper's internal inventory system. That is to say, linking of GTIN numbers to an inventory system will, at a minimum, require either separate systems of identification (using internal product ID numbers) or a manual process of matching each synchronized GTIN and company prefix to a back office system by hand. For some members of the supply chain (such as distributors), this process will entail manually linking thousands upon thousands of unique codes to internal item numbers. The PTI documentation regarding external product substitutions for the PTI refers to "substitutes" as a product that can be substituted for another inasmuch that it does not "compromise the specification or quality of the product" (PTI Steering Committee 2009). Considering that many of these thousands of items will fall into the category of substitutes, linking GTIN's to existing systems will be a tedious, expensive, and arduous task.

While the PTI has provided a common nomenclature and schema for product characteristics, it simply does not fully establish an approach for uniquely identifying products throughout the supply chain that will improve the speed of a recall. Utilizing a common nomenclature to establish standardization and then creating unique reference numbers for every type of product shipped from every company that ships the product is analogous to differing interpretations of language and slang terms across countries that speak the same language but with different dialects. If the goal of future product traceability is a more rapid and limited recall, simplicity and uniformity in differentiating individual products should be the goal of assigning reference numbers within a given commodity group. Allowing each company to individually determine the

level of detail to be used in assigning reference numbers for each product introduces a great deal of ambiguity and confusion into the system.

### *Goal I.a.3. Lot or Batch Information—Description*

Lot or batch information should be unique to the degree that it segregates contaminated products to the maximum scope through which cross contamination could occur. For example, in some commodities this would constitute identifiers at the level of an individual field where contamination could be caused in a small portion of the field (e.g. droppings from wild pigs) or could be the caused by something that affects the entire field, such as a contaminated water source. The level of uniqueness for the lot should also represent the lowest common denominator of potential contamination (as in the case of water contamination). In many situations, the cause of contamination could be either a single field or multiple fields. However, the lowest common denominator is that which provides the narrowest scope. In other contexts, the lot or batch identification would be defined by a totally different set of parameters (for instance, cut and bagged mixed lettuce where the end product could consist of multiple varieties from multiple fields, farms, and/or growers).

The key point in utilization of the lot or batch number is to minimize the impact of a recall by narrowing the scope of the product that is implicated. Additionally, the lot or batch number becomes extremely important when products are processed (i.e. cut or comingled) such that a recall from a single distributor does not cause a much broader recall of processed products. If data on lots and batches is not consistent and does not follow the product, FDA's efforts to trace the product back through the supply chain may cause them to lose the trail of the product; the FDA may not know that they are still tracing the right product (USDA 2009a)

Additionally, it can be argued that simply following a product by its "product" characteristics may lead to a much wider recall than it would with a lot or batch number attached to it. For example, many trucks carry multiple commodities from multiple companies and many of the products are from multiple original lots. Thus, a trace-back for an apple that may have been caused by a problem on a single truck where temperature controls were not monitored could lead to a much broader recall of apples from one shipper or even for the entire apple industry. A similar situation occurred with spinach products in 2006 where an isolated problem was initially attributed to the entire spinach supply and resulted in a very broad recall of the entire spinach crop across the U.S.

### *Goal I.a.3. Lot or Batch Information—Assessment*

Interviews with shippers showed a wide variety of philosophies in lot/batch number assignment. Some shippers have lot/batch number schemas that include very detailed information such as grower, field, date of harvest, crew and machine while others referred broadly to lots as windows of time (i.e. a single day of harvest) or a single ranch. The approach each shipper took in assigning lot or batch numbers was based largely upon their own processes and needs and not on any uniformity principle. Although the lot or batch identification is a key element to traceability, the PTI action plan has provided no guidance in establishing uniformity in lot/batch numbers. The resulting variety of detail and lack of consistency is the current outcome.

### *Goal I.b. Common Level of Detail—Description*

In many ways, the level of detail is an integral part of the interpretation of traceability nomenclature. Depending on the commodity, post-harvest processes, and location in the supply chain (i.e. shipper's warehouse, processor's cutting line, or grocery store shelf), fresh produce has many levels of detail. In some cases, product is shipped and/or stored in bulk bins. In others, the product is stored in cases and palletized. Many commodities are placed on grocery shelves in bulk with no packaging (e.g. much tree fruit).

Interviewees were relatively consistent in indicating that some method of implementing precise labeling and tracking at the unit level (i.e. on each individual potato or carrot) would allow investigators to minimize a recall if the consumer still had a sample available of a suspected food product. Of course, in practice this would rely on consumers possessing whatever portion of the product is remaining. Additionally, the reality is that labeling each individual type of produce by unit is neither feasible nor effective for a number of reasons, as both shippers and distributors pointed out. First, it is physically impossible to affix individual labels to many items such as bulk carrots or green beans. Second, traceability would not be improved through the supply chain by labeling individual items as they are shipped and moved through the supply chain in cases. Third, considering that a major problem for investigators is that consumers either don't remember what they ate in detail or have disposed of the product by the time regulators perform interviews, individual item labels don't do much to help narrow an investigation (USDA 2009a).

In the end, a trace-back that accurately identifies a source product that has been contaminated after the product has been consumed or disposed of (across the supply chain) does nothing to mitigate the spread of an outbreak. Trace-backs must occur with both accuracy and speed. In the world of perishable fresh produce, traceability yields little gain to consumers if product has already expired or been consumed by the time at which it is implicated. In order to implicate the specific source of an outbreak, an investigation must either match a strain of illness from patients to a particular food product, or investigators must find a statistically significant link between geographically dispersed clusters of the same strain of a pathogen in products consumed by those patients. In other words, narrowing the list of "possibilities" by having some idea what each patient consumed to find commonalities and then searching for common sources of those common products could drastically narrow the search. In order to establish this link, investigators must first have the ability to narrow the options. As customers often don't remember specifics of the products they have consumed, they are more likely to remember in general what they consumed (i.e. a bag of lettuce as opposed to a specific variety of lettuce) and where they shop (USDA 2009a). In this case, with the knowledge of what type of fresh produce (i.e. which specific types of romaine lettuce as well as which specific lots each of romaine lettuce) they have a heightened ability to statistically implicate a very narrow line of products and lots. Knowledge of what products could have been consumed at a narrow level of detail gives investigators an opportunity to not only exclude other products, but also to follow each product's path back through the supply chain for source commonality.

Therefore, the ideal level of detail for the application of nomenclature is that which is capable of both 1) narrowly identifying a specific company's lot-specific product (i.e. the lowest common denominator), and 2) being applied at a level of detail such that it is both identifiable

and visible to the largest number of supply chain members as any other form (i.e. pallet level of detail vs. case level of detail).

The use of data modeling to map commonalities between products has been tested and proven to be both successful and rapid, though the actual process of gathering and standardizing data (a necessary process) has caused long delays in data processing. Researchers working with Harvard University spent weeks “cleansing” data such that the reported information was fed to a computer modeler in a standard fashion. Once standardized, a visual trace-back and implication was possible in an incredibly rapid manner. Thus, the more data available in a pre-standardized format (such that investigators need not “cleanse” the data) the more rapidly one can expect statistical analysis to yield results for implicating an individual source product while also eliminating many others (McEntire J. C. et al. 2009).

#### *Goal I.b. Common Level of Detail—Assessment*

The PTI posits that, while item level traceability may occur in the future, the case level of identification makes the most sense at this time. The case level 1) may be implemented in a way that is not prohibitively costly or time consuming; 2) may be applied to all produce, including bulk produce that is too small or in some way cannot accommodate a unit-level sticker; and 3) is the lowest level of detail that is both feasible and handled by each member of the supply chain.

The debate over level of detail is one with fiercely differing views across the supply chain. Many individuals in the supply chain question the reliability of case-level traceability because produce that arrives at a retail store in a case is seldom purchased by consumers in that case. That is to say, there is still a degree of variability in the implication of a single product and/or lot because products from different companies and lots are comingled outside of the box for consumers to purchase. The argument is that case-level traceability does not allow regulators to implicate individual products in any narrower scope than they is currently available.

Based upon the methodology that is used in the epidemiological investigations that precede and accompany trace-back investigations, a broader outbreak of a specific illness provides many more points of data. For example, if (at a given time) there are twenty company prefixes in commerce for a given product and each of the twenty company prefixes are accompanied by five different lots that were received and placed into commerce at the store level, regulators are provided a great deal of data in which to build a confidence interval to statistically determine the likely culprit of contamination.

To illustrate, consider a nationwide outbreak in which several commodities are suspected. If data is readily available that allows investigators to view the potential products and associated lots for each of these commodities, then they can begin to establish commonalities. For example, an instant illumination of each product flow provides the possibility of finding a common point of contamination (a particular warehouse, truckload or origin lot). This allows investigators to limit the scope of an investigation by quickly focusing on the commonality and pulling only that product from commerce rather than causing a recall for an entire commodity or multiple commodities (as has happened in recent history).

Considering that the greatest damage to a commodity supply chain is the result of a massive outbreak (such as the 2006 E. coli outbreak in spinach), the case level as proposed in the PTI seems to adequately provide regulators with a great deal of uniform, readily available data that identifies product in 1) the narrowest feasible scope (i.e. each individual company's product by lot/batch) and 2) at the lowest level of detail utilized by each member of the supply chain (and which is subsequently recorded).

#### *Goal II. Linking Data Elements—Description*

The FDA has also noted that it is not only important that there be standardized data elements, but also linkages between those data elements from farm to fork. More specifically, the FDA has made the point that while standardized data elements are incredibly important to any traceability system moving forward, they “can't stand alone” simply because the existence of a data element does not create a link for the product across the supply chain (USDA 2009a).

Additionally, shippers with FDA investigation experience pointed out that it is imperative that fresh produce be traceable first by the *physical* path it traversed through the supply chain. That is to say, a trace-back motivated by existing documents such as invoices and bills of lading are suited to trace product back at the transactional and monetary level. As noted in a recent study (Alliance for Food & Farming 2010), contamination of food product can happen at any point in the supply chain in which the product is handled or moved (for example, a cooling failure or exposure to other harmful substances, etc.). Establishing a statistical link between individual lots of product to implicate as precisely as possible links between physical paths of multiple products/lots must be available and accurate.

As pointed out by the International Foodservice Distribution Association in their public response to the FDA's request for comments on traceability, the need for each link in the supply chain to maintain any list of ingredients for each product received is neither feasible nor helpful in the trace-back process (IFDA 2010). Rather, the organization in the supply chain that reconfigures or remanufactures the product should be responsible for establishing the link between each source product and the final lot/batch produced and shipped. As such, for an accurate and rapid recognition of each individual product's movement through the supply chain, there needs to be an electronic link between individual products used as ingredients and the lot/batch produced such that a trace-back can effectively locate product still in raw, bulk form or as part of a comingled or remanufactured product.

#### *Goal II. Linking Data Elements—Assessment*

The PTI provides recommendations for linking data elements (such as reference numbers) across the supply chain through the use of tools provided by GS1. GS1 can, through the use of standardized company codes and nomenclature, provide an electronic means to link identifiers to actual descriptions of the company and product. It is unclear at this stage to what extent this tool is being utilized through the supply chain and unclear that it is the methodology of choice for organizations across the supply chain. While it is reasonable to assume that the PTI itself should prescribe a specific means of linking data elements to the description of those data elements (i.e. a reference number linked to the description of that product), it must be the goal of any traceability

initiative to work across levels of the supply chain to establish commonality. A manual system (i.e. e-mailing spreadsheets with new reference numbers) of exchanging data elements that are intended to provide links between systems is cumbersome at best and, as evidenced through interviews, not currently effective. In most cases, there is confusion as to where reference numbers are to be sent and who needs to receive them.

The concept of linking data elements is also complicated by the of “brand owner” as the preferred methodology of company prefix. The utilization of company codes that clearly indicate the physical path (i.e. each warehouse through which the product flows) allows investigators to rapidly trace multiple products to establish commonality. However, the use of the brand owner as *the* company identifier creates a situation in which the datasets for some product will show the physical path by linking the company prefix of each location through which the product travels to the company prefix of the owner of that *location*. As currently implemented and recommended in the PTI, the use of company prefix simply provides a link back to the grower or prior processor of the produce and provides no unique company and/or location information for those locations in between the origin and ultimate consumption of the product. Considering that recent research suggests that a majority of outbreaks are caused by factors occurring after the product is grown, the use of currently proposed methodology appears to provide sufficient data on only a subset of locations (Alliance for Food & Farming 2010). Additionally, the use of “brand owner” in the case of private labeling will not go so far as to even provide that link. As currently written, the use of company identifiers is well employed to uniquely identify the individual product, but not extended to the degree that it provides a full product path dataset throughout the supply chain; the currently proposed labeling will not consistently lead investigators to a point in the supply chain (i.e. original grower or modifier) and will fail to uniquely provide linkage from location to location between farm and ultimate consumption.

In order to effectively trace product through the supply chain, it is imperative that the issue of tracing physical product flow versus the monetary flow of transactions be addressed.

### *Goal III. Standardization of Reporting Methodology —Description*

In a major outbreak, regulators face multiple challenges in terms of information gathering for trace-backs. Among these are the window of time in which each organization has to report traceability data as well as the wide variety of both information formats and reporting formats. Thousands of pages received in differing reporting formats and mediums (i.e. fax, mail, photocopies, etc.) translate into more time assembling and interpreting the data. It is not only the access to and availability of uniform product information that is important, but also the uniformity in which the data are received. The Harvard Tomato study reinforced the need to establish commonality both in data and in reporting (McEntire J. C. et al. 2009). Common nomenclature on its own does not mean that the data reported is uniform (i.e. each individual back office system produces reports that have unique layouts, characteristics, descriptions, etc.) Additionally, recent outbreaks have proven that even a single day saved in the discovery and implication can make a difference in the outcome of an outbreak and, most importantly, in lives saved. Regulators must have rapid access to data that is not only collected in a uniform nomenclature but reported in a uniform manner as rapidly as possible. Electronic transmission is the fastest possible mechanism, assuming it is reported uniformly across the supply chain.

A major concern expressed by many of those interviewed is privacy. This was evident across the supply chain as many individuals expressed a concern for the privacy of proprietary trade data because of the potential that this proprietary data may be made public if the information were to become readily available to regulators in a “cloud-based” system. Shipments between supply-chain members constitute trade secrets and exposure of these “secrets” to competitors presents a major challenge in maintaining competitiveness. There is widespread fear that traceability data that is accumulated in a single location or available “on-demand” will be used for purposes other than tracing product by regulators and that shipment and product data may fall into the hands of a company’s competitors. In an era of enhanced scrutiny and availability of data from regulators through means such as the Freedom of Information Act, organizations have a high level of concern that widely available data will not remain private and be used only as promised. While the use of electronic reporting in a standardized format for the traceability nomenclature is ultimately an important part of traceability, the issue of information privacy must be addressed. Based upon information from interviewees, a method for reporting in which regulators may receive rapid responses to standardized requests while simultaneously minimizing the chance of potential privacy violations for supply chain members through exposure of non-necessary data is ideal. A higher level of legal protection ensuring the protection of trade data will lead to a more cooperative industry and a greater likelihood that the necessary data will be provided.

#### *Goal III. Standardization of Reporting Methodology — Assessment*

The PTI does not, in any way, suggest or speak to a reporting methodology. The absence of standardized electronic reporting of data is an important method with which to ensure that data is “cleansed” so that regulators utilize it effectively. While the PTI suggests that data be recorded electronically, it provides no guidance whatsoever as to what additional information the dataset should include and no method or recommendation for the provision of data to regulators. Lack of universal company prefixes for each firm in the supply chain that handles the product adds additional ambiguity in the linkage of products from one supply chain member to the next.

The spinach recall of 2006 made clear that many hours were wasted simply sorting through the wide variety of data formats received (i.e. fax and mail) as well as differing formats and descriptions of data elements used in internal documentation (i.e. bills of lading and invoices). These wasted hours resulted in an investigation that proceeded much more slowly than would be the case with standardized data. The *storage* of standardized data as described by the PTI plan is only a first step toward improving the speed and accuracy with which a recall occur. The *presentation* of that data in relation to the data stored by other members in the supply chain is paramount in speeding up the process. It is critical that the data be both standardized *and* reported in a standardized manner.

#### *Goal IV. Equal Recordkeeping Requirements across the Supply Chain — Description*

The comingling of fresh food products at any level of the supply chain may be cause for worry when not properly documented. A 2008 outbreak of E. coli O157:H7 in ground beef was traced back to a common retailer who didn’t keep records (called “grind logs”) of which lots of beef were comingled into packages of ground beef. As a result, the Food Safety Inspection Service

(FSIS) was unable to trace the contaminated product back to its source to ensure that no additional contaminated beef from that lot was still being sold in other locations (USDA 2009a).

Grower/shippers indicated emphatically that they were very concerned that all organizations will not be expected to follow the same guidelines. Specifically, they expressed concern that small companies need to be held to the same standard as large companies. This concern was expressed not so much as a matter of fairness but rather with an eye towards effectiveness. In a supply chain with many links between the source and the ultimate consumer, a single broken link may cause the trail to be lost in a trace-back. If small farms, small distributors, and small retailers are allowed to bypass any requirements to track product and provide product source data that would make a trace-back and subsequent trace-forward more effective, the implementation across other members of the supply chain becomes compromised. In other words, a partial trace-back including only members of the supply chain deemed “large” will leave holes in the investigation and potentially cause inconclusive implication and more widespread recalls.

Pressure from industry partners and buyers may also serve to “raise the minimum bar.” Shippers who do not comply with existing regulations may be forced to, at a minimum, increase the effectiveness of current traceability programs. However, it was noted by multiple supply chain members that large upstream supply chain members are the key to providing appropriate pressure to ensure widespread adoption of voluntary new data standards. While small buyers may not have the ability to influence a large distributor or shipper’s operations, a very large buyer can exert such pressure. In this way, consistency on the part of upstream members is imperative if standardized data is expected to be broadly adopted. Almost without exception, it was noted in interviews that prior initiatives first endorsed by major downstream purchasers (such as the use of databar technology) were often cast aside in the instance of cheaper alternatives not meeting the requirements.

Similarly, each time a product is introduced into a new environment, data collection and retention requirements should also be applied in a uniform manner across each handler of the product, whether or not the product was reconfigured. Whether the product is packed, processed, distributed or simply handled and not reconfigured, each level of touch presents an opportunity for the introduction of contamination. In devising full-chain traceability for perishable produce items, it must be possible to track produce at any location where there is an opportunity for contamination.

Different members of the supply chain suffer in more or less dramatic ways depending on two factors: the quantity and quality of traceability data maintained as well as level in the supply chain. In defining appropriate quantity and quality, it can be noted that an effective trace-back procedure relies on a *quantity* of data sufficient to follow individual product lots from entry (source) to exit (recipient) in a given location while the *quality* of data would allow specific identification for minimal impact in a recall situation. Additionally, the level in the supply chain can dictate the stakes involved in a trace-back. To illustrate, we describe two fictitious examples related to us by several of our industry experts. In both examples, members of the supply chain who dutifully record and maintain trace-back information are harmed by those who do not.

1. Many growers/shippers comply with recordkeeping and labeling by application and maintenance of relevant traceability data by lot/batch. In the event of a recall, product is received from grower/shippers who have provided sufficient information as well as those who have not. Because there is only a partial dataset available for trace-back, a widespread recall on a commodity is initiated, harming all grower/shippers equally.
2. Trace-back information is provided and accurate at a grower/shipper level but maintained only partially at a distribution or retail level. In the event of an outbreak, there is not sufficient data to implicate a single source due to lack of traceability records between distribution centers and individual retail outlets such that all product must be recalled for a given commodity or commodities. While all members of the supply chain bear some cost in the recall, the ultimate burden is upon the grower/shipper who must refund the cost of the product through the supply chain in addition to performing a recall.

While these two examples are not intended to provide the full breadth of potential issues in which some players “follow the rules” while others do not, they are provided to support the idea that traceability, in order to be effective, must be implemented (without exception) chain-wide.

#### *Goal IV. Equal Recordkeeping Requirements across the Supply Chain —Assessment*

The future goals call for a full trace of product from one end of the supply chain to the next such that any link in the supply chain in which contamination is possible may be identified. However, the PTI allows certain supply chain members to forgo recordkeeping for the purpose of cross-docking. While product is handled by a third party, there is no requirement for recordkeeping. This physical “stop” along a fresh product’s trip to the consumer presents an opportunity for contamination. To ignore record keeping requirements at any physical location is to reduce the transparency of traceability data and allow for a greater possibility of an untraceable contamination. This cannot be the case if the data provided by the PTI is to be complete for use in investigations.

Additionally, the PTI utilizes the Bioterrorism Act’s definitions of exemptions from recordkeeping requirements; this means that small grocery stores, small farms, and direct-to-consumer restaurants have limited or no recordkeeping requirements. These consumer-facing companies are an important link between consumer illness and the source of food from which the contamination occurred and therefore must be included in any recordkeeping requirements for an effective trace-back system.

#### *Goal V. Visibility —Description*

A final and, perhaps most difficult, part of traceability is the concept of visibility to and the perception of consumers and regulators. If consumers and regulators do not trust the accuracy of a new traceability process, widespread recalls will continue to occur and consumers will continue to avoid the purchase of food not affected by a recall merely because it is the same commodity as the contaminated product. Consumers must ultimately have the perception that the traceability system in place across the supply chain will help ensure that contaminated product will be removed from commerce rapidly and accurately, thus minimizing reputational and financial dam-

age to industry. Additionally, consumers must have the *means* to know what food is affected in as detailed a manner as possible. If consumers only know that bagged spinach is affected but have no knowledge of brands, ‘best-if-used-by’ dates or other identification, they will likely cease to purchase bagged spinach products and the entire industry will suffer. Because of the experience with recent major outbreaks (such as the spinach recall of 2006), wariness by consumers and regulators, in terms of trusting traceability records, has continued to grow. If consumers don’t trust the supply chain to accurately perform a recall such that contaminated food is pulled from commerce effectively, many consumers will cease to purchase that commodity for fear that they can still get sick and/or die. This concept of visibility and understanding of food safety on the part of the consumer was touched upon, in some way, in almost every interview conducted.

#### *Goal V. Visibility—Assessment*

The concept of providing visibility is a difficult one, probably the most difficult of the future goals. In this regard, it is also difficult to expect a plan such as the PTI to have visibility integrated into its outline. Visibility, in the case of the PTI, may be more in the form of recalls becoming less visible with its implementation. This is dependent upon regulators utilizing the system, narrowing trace-backs more rapidly, and outbreaks being minimized as quickly as product can be pulled from commerce. To this end, this goal will be met so far as the PTI is successful in reducing the publicity and damage from foodborne illness outbreaks.

### **Recommendations**

In the previous section of this paper, we develop future goals for an ideal trace-back system for the fresh produce industry and assess to what extent the PTI has the potential to achieve these goals. In this section, we establish a set of principles as recommendations for moving forward. These principles are not intended to be individual steps towards meeting the future goals identified in this research. Rather, they are meant to be high level guidelines that will help meet the future goals and fill the gaps identified in the PTI.

#### *Recommendation 1: Stick to Uniformity Principles*

In order to effectively utilize data analysis techniques, it is important that investigators not waste valuable time “connecting the dots.” If a principle is applied to one sector of the industry for recordkeeping, it should be uniformly applied to other sectors such that records are utilized in a consistent fashion. The point of traceability is to implicate the narrowest line of contaminated product(s) possible such that public health as well as financial damage may be limited throughout the industry to the maximum extent possible. A standard should be chosen, applied across the board, and used consistently. This includes identification of locations and companies that handle the product, identification of one product from another, and identification of source or origin of lots and batches. This uniformity needs to exist, without exception, between growing and ultimate consumption. Codes representing these elements should be universally recognizable and their meaning must be commonly understood across the supply chain.

### *Recommendation 2: Standardize Product Reference Number Elements*

Related to uniformity but specific to one part of the nomenclature is the issue of assigning unique reference numbers. Unique reference numbers should identify the product uniformly. Otherwise the implementation of tracking systems will become monumental in scope and archaic in interpretation. A system that utilizes ten to twenty individual product codes for the same essential product for tens of thousands of products will undoubtedly lead to confusion on the part of regulators. The industry must settle on a common nomenclature for the sake of efficiency and the good of the industry. By reducing the ambiguity in defining products, the overall complexity of the system is reduced (both in implementation and ultimate use). Minimization of redundancy and interpretation should be a major goal in traceability data. Failure to clarify the interpretation of a product description simply because a standard level of detail was never agreed upon will exact a high price in terms of the speed and accuracy of an investigation.

### *Recommendation 3: Create a Reporting Mechanism for Investigative Purposes*

Perhaps the most troubling aspect of the PTI is that there is not a single mention of reporting or recommendations or guidance for doing so. In reality, the FDA has recently made strides toward standardized technological reporting with the Reportable Food Registry. If the industry is working towards creating the dataset *for* the government, they should know that it will in fact be used *by* the government. If the industry implements the PTI and proceeds to print out volumes of reports (each in their own company-specific format) to mail and fax to the FDA, the industry has gained very little. In the case of a food-borne illness outbreak, time is of the essence. It is critical that a method for rapidly communicating information to the FDA be developed so as to speed up future investigations, and reduce human illnesses (and deaths) and industry losses. There must be a uniform method of rapid data delivery to the FDA from each point in the supply chain in order to successfully minimize traceability investigation timeframes.

### *Recommendation 4: Create an Environment of Open and Transparent Communication*

It will be critical that industry members within the supply chain and across commodities find an effective means of communication. It is clear, as discussed above, that issues of standardization and uniformity not directly met through the PTI must be addressed. However, it is also clear that it is not realistic for the representatives that form the steering committee to universally address these issues across all commodity groups. Industry members both within levels and across levels of the supply chain need to be in communication regarding the needs and uses of the datasets. Understanding the expectations and realities of the data that must be captured will go a long way towards collecting and reporting it. In this way, commodity specific associations should be involved in formulating a traceability plan for the future. If the common nomenclature to be utilized is that provided through GS1, leaders and representatives across commodity groups will be prepared to formulate methodologies for such items as reference numbers and universally applied levels of detail for each commodity. Without proper communication and cooperation, the industry will simply create another layer of complexity using a new nomenclature.

## Concluding Remarks

The Produce Traceability Initiative establishes a necessary “first step” towards creating a common nomenclature and methodology for transferring that nomenclature throughout the supply chain. For this reason alone it will provide a valuable mechanism for traceability. It is evident that the committee that first created the PTI realized that it would not fully answer the call of a future traceability system from its first inception based on its recognition as a “living” document.

There are gaps in the PTI that need to be filled before it can effectively fulfill its lofty goals, goals that will not be met by implementation in its current form. One major issue that has arisen is that implementation is happening in isolated corners rather than as a commodity industry group. Until better communication is established between members of the supply chain, the implementation, understanding, and use of the PTI will be difficult. If this communication does not occur, gaps may never be filled and this may be yet another costly initiative that goes unused or underutilized. The utilization of data collection techniques to narrow the scope of recalls depends on both the quality and quantity of data. If the industry is not compelled to store and produce this data rapidly, the PTI will fall short of achieving its goals.

It also remains to be seen whether or not the information that is provided by the PTI will be communicated and/or used by the FDA for investigative purposes. Even if the data is created and stored industry wide, a methodology for reporting by industry and use by investigators must be established or the standardization called for by the PTI will fall short of accomplishing the PTI's objectives.

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