COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY

Traceability (Product Tracing) in Food Systems: An IFT Report Submitted to the FDA, Volume 1: Technical Aspects and Recommendations

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Executive Summary

Institute of Food Technologists (IFT) examined traceability (product tracing) in food systems under contract with the U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition.

IFT collected product tracing related information from industry representatives through telephone discussions and meetings with targeted groups, and from a number of other resources. A total of 58 food companies categorized as produce (38%), packaged consumer foods (14%), processed ingredients (7%), distributors (5%), foodservice (17%), retail (12%), and feed (7%) were consulted. Nonfood industries examined included automobile, pharmaceutical, toy, parcel, clothing, and appliance. These industries use diverse product tracing methods, some of which are technologically sophisticated. An evaluation of the motivation in each industry, and the problems that product tracing was used to address, leads to an understanding of the reasoning for the use of particular product tracing solutions. The challenges faced within the food industry are unique and will likely require a different kind of solution to trace products. IFT also examined regulations, standards, and initiatives pertaining to product tracing around the world.

Overall, all food companies participating in this study acknowledge the importance of an effective (rapid and precise) product tracing system in safeguarding their supply chain. The majority of the companies have recordkeeping systems in place that range from manual to sophisticated electronic-based systems. The level of sophistication appears dependent on company size, with the larger companies having more sophisticated systems, although paper records were used in virtually all segments of the food industry examined. Most of the companies have great confidence in their current systems to provide effective product tracing. In fact, those covered by the BT Act of 2002, which requires them to establish and keep records on immediate source (1-step back) and subsequent recipient (1-step forward) for their products, currently consider their companies to be in full compliance.

Significant variability in current product tracing practices was observed among various segments of the industry, likely resulting from the complexity of food systems. However, there is great commonality in issues that complicate product tracing, which are mostly centered around types of data collected, how the data are captured, and data sharing within the facility and among trading partners. The general lack of consistency in types of data collected, as well as lack of definitions of key terms such as "lot" or "batch" appears to be a major hindrance to effective product tracing.

IFT found that data capture is achieved through several media types of which the most common are: pen/paper (alphanumeric notes), bar codes, radio frequency identification (RFID), and electronic systems. In rare cases in the food industry, but more common in nonfood industries, are systems based on vision/imaging, dot peening, and laser etching. The speed at which information can be retrieved and communicated varies with the type of medium used. There was great disparity in the types of information shared among trading partners. Data elements that are critical to product tracing, such as lot number, are seldom recorded or communicated. Information relevant to product tracing is transmitted through commonly used paperwork such as invoices, purchase orders, and bills of lading that may be in paper or electronic format. However, lot numbers are generally not included in these transmissions. For many food companies product tracing is treated as an added function to their existing management systems such as inventory control, warehouse management, and accounting, and therefore discerning costs related to product tracing is difficult. Some segments, such as retail and restaurants, do not generally keep records with lot-specific information and rely on their suppliers for this information.

Certain segments of the food industry are currently working on initiatives to streamline product tracing in their respective sectors. Most of the initiatives are spearheaded by industry trade associations. Similarly, within the past few years numerous companies have begun developing proprietary traceability solutions based on a variety of approaches such as data transfer platforms, system software, and media such as bar codes. The majority of the "solution providers" do not market themselves as providing product tracing exclusively, but as a component of their product portfolio. However, most food companies reported that these services would be difficult to integrate into their existing processes and systems.

Implementing the practices recommended by IFT will have an economic cost to the industry, but may also have benefits, including improved supply chain management, inventory control, access to contracts and markets, more targeted recalls and hence lower costs to recall. Firms could also benefit by protecting brand name, maintaining consumer confidence, and reducing possible liability claims. Furthermore, product tracing could allow the exclusion of a firm's product from an investigation. A rapid response to an accidental or intentional contamination or other triggering event through improved product tracing would yield social benefits beyond the direct benefits and cost reductions to the firms.

Despite significant firm level and aggregate benefits, the costs of enhanced product tracing can be significant. This is particularly true for firms where substantial amounts of ingredients are processed and need to be tracked into finished products, or when firms rely on paper-based systems. Costs of available technologies and services to provide firm level product tracing are likely to decrease with increased competition in the market. There are also many systems in current use that serve other business functions (for example, accounting, inventory control, and so on) that may be capable of recording key data elements at minimal expense. Companies will incur product tracing costs every year, while the likelihood of an outbreak per year is fairly low, and varies per product category or sector.

An IFT expert panel reviewed the data that were compiled during the examination of product tracing systems and developed recommendations to improve the breadth, depth, precision, and access of information. Overall, the panel felt that setting clear objectives for those in the food supply chain, and allowing the industry to determine how to reach those objectives, was the most appropriate approach to effective product tracing. Principally, the system should be simple, user-friendly and globally accepted, as well as have the ability to leverage existing industry systems. The responsibility should begin with the first party that closes the first case (for example, ingredient) and end with the party that opens the case before product is made available to consumers (for example, restaurants, grocers, and so on).

Recommendations

1. **Required key data elements**
   Upon request during a traceback investigation, the following data elements should be made available to the FDA by the applicable supply chain partners (from farm to the retail/foodservice outlet). The nature of the key data elements is such that linkages are maintained, allowing a product to be traced through the supply chain. For example, each time a lot number is changed, the original and resulting lot numbers must be recorded. Similarly, if a lot number is unchanged, but the product moves between facilities, this

information must be recorded so that the path of the product can be followed. The key data elements that should be provided in an electronic form using an approved standardized format, for each case containing a product of interest include:

- Physical location that last handled the product, whether the manufacturer or not, and, if applicable, contact information for the broker who handled the transaction
- Incoming lot numbers of product received
- Amount of product manufactured or shipped
- Each physical location where cases were shipped (including individual retail and foodservice locations)
- Lot number(s) shipped to each location
- When (date/time) product was received and/or shipped
- For producers, processors, repackers, and others who transform products:
    - When (date/time) each lot was manufactured (or harvested)
    - All ingredients used in the manufacture of the product, along with their corresponding lot numbers (not item code), the immediate source of the ingredients, and when they were received.

As a best practice, the lot number and name of the manufacturing facility should appear on each case of product, and the lot number(s), quantity, and shipping location should appear on invoices and bills of lading.

2. Recordkeeping

Each facility handling a product must record its specific transactional portion of the information specified in nr 1, above, for each critical tracking event. CTEs are those instances where product is moved between premises, is transformed, or is otherwise determined to be a point where data capture is necessary to trace a product. The information recorded at CTEs provides the links within the product supply chain. Neglecting to capture appropriate data elements at a CTE will result in a break in the product tracing chain, since CTEs capture changes in information, such as changes in lot numbers that provide the link between products within a product pathway. With regard to product transformation, information captured at those CTEs must be able to accurately match ingredients or incoming material, at the lot level, to outgoing product. Each lot number of each case of shipped product should be recorded, even if "first in, first out" practice (FIFO) is adhered to. Records should be maintained for 2 y or the shelf life of the product, whichever is longer. Each entity must provide this information to FDA, as requested, in an electronic format within 24 h; however, the way in which each firm captures and records data internally is not prescribed. A facility may choose to maintain the key data elements for each CTE in a centralized system or may silo the information according to the CTE. For example, key data elements for receipt of material may be maintained in a system dedicated to receiving while recording the use of ingredients may be maintained in a batching system. Keeping the key data elements separate for different points in a process does not affect a firm's responsibility to capture the key data elements that link products through the supply chain.

Internal Product Tracing

The ability to trace products internally accurately must be maintained by food companies. For products that do not undergo further processing or transformation (for example, the case is not opened) a one-to-one relationship between incoming and outgoing lots must be maintained. For example, if a pallet contains cases with different lot numbers, those cases will need to be followed individually through a system. Incoming lot numbers are one of the key data elements that need to be captured and made available to FDA in an electronic form within 24 h of an official request. From a practical standpoint, recording each lot number of each case may require additional labor and slow operations. Since this information should also be printed on paperwork that accompanies or is related to the product, examining lot numbers in a pallet should be done as verification. Mechanisms exist whereby a pallet label can readily communicate the information for each case without the need to record information from every case. If a pallet comprising cases with different lot numbers is divided into individual cases, simply providing the various locations that received cases from the pallet (for example, the recipients), without indicating which lot was shipped to each location, results in a loss in the ability to trace product. In the case of a mixed pallet, shipping records must show where the cases were sent according to the lot number on the case. Lot numbers should also appear on the invoice, bill of lading and/or, purchase order or other accompanying or related paperwork.

When minimal repacking occurs for perishable products (for example, to remove items that spoiled prematurely or are otherwise defective), a one-to-one lot ratio should be maintained. In other words, if there is a 5% defect rate, 100 cases of lot "a" should become 95 cases of lot "a," instead of generating 100 cases of a new lot that are "mostly "a" with a little "b."

3. Approved standardized formats

There needs to be agreed-upon nomenclature and standardized ways of expressing information (for example, dates should be expressed in a single format, not 1/3/09 in some instances and January 3, 2009 in others). For each element above (quantity, location, lot number, date, and so on) there are multiple globally recognized standards; however, in many parts of the food industry, these standards are not used. For each data element, a limited, select set of standards will need to be identified as acceptable ways to communicate information.

4. Electronic compared with paper

Access to information in a timely fashion, when requested, is best facilitated by data being available in an electronic format. For operations not currently using electronic databases or other electronic systems, who wish to continue using a paper-based system, the transfer of data to an electronic format should be required. This transfer may be done through 3rd parties, but would be required to be done regularly, such as daily, to be kept current.

5. Required audit

The ability to trace product should be part of a standard 3rd-party audit, so that the correct capture of the data elements specified can be determined. The appropriate identification of CTEs, and adherence to accurate internal tracing should also be assessed.

6. Training

Guidance should be developed that details how CTEs should be identified, and provides definitions for terms such as "lot." Educational product tracing compliance modules should be developed and all segments of the food industry and regulatory community should be trained in their use.

Core Recommendations

Each supply chain partner must:
- Identify Critical Tracking Events in order to trace product
- Record standardized key data elements for each Critical Tracking Event that link incoming with outgoing product, whether product is transformed (internal tracing) or changes location (external tracing)
- Provide FDA with key data elements in an electronic form for each Critical Tracking Event within 24 hours of a request

Standardized ways of expressing key data elements should be agreed upon

Education on Critical Tracking Events and key data elements should be developed, and evidence of appropriate implementation should be part of standard audits

Background: The U.S. Food and Drug Administration (FDA) through a 5-y contract (nr 223-04-2503) with the Institute of Food Technologists (IFT) issued a task order to evaluate product tracing and trace back systems in the food and feed supply chains and provide recommendations. Specifically, IFT was tasked to conduct an in-depth review of industry practices and various processing or engineering technologies used to track the movement of food products, forward through the supply chain and back to the original source. Additionally, IFT performed an in-depth review of the costs associated with the identified product tracing systems and technologies (Volume 2). The scope of the study included a review of food and nonfood industry product tracing practices in the United States and other countries. This information can be used by the FDA to evaluate the relative public health, economic, and shock consequences (that is, risk) of product tracing systems in the food and feed continuum.

1.0 Background as Provided by U.S. Food and Drug Administration (FDA) to Institute of Food Technologists (IFT)

In the past, FDA responded to food safety problems with contaminated spinach, lettuce, peanut butter, and more recently with cantaloupe and tomatoes. Whether contamination is unintentional or deliberate, it is quite evident that there is a need to respond more quickly and communicate more effectively with consumers and other partners.

U.S. agriculture is a $200 billion business with over $55 billion in exports each year. Agriculture has a $1 trillion value when the infrastructure, land, and other assets are included and provides 22% of all jobs. The United States is the largest producer of food and agriculture products in the world. Combined, agriculture and food production constitute the nation's largest business. The United States has over 500000 farms, and over 6000 meat, poultry, and egg product and production establishments.

The Federal Government provides advice on healthful eating, including consuming a diet rich in a variety of fruits and vegetables, through the Dietary Guidelines for Americans and the related MyPyramid food guidance system. In response, per capita consumption data show that Americans are eating more fresh produce.

Marketing channels have undergone considerable change since the late 1980s. Prior to 1987, fresh fruit and vegetable markets were more fragmented; most transactions took place between produce grower-shippers and wholesalers on a day-to-day basis, based on fluctuating market prices and quality levels. Today, a typical produce sale may take place between a multi-product grower-shipper and a large supermarket retailer under a standing agreement or contract specifying various conditions and terms, including marketinvvg services provided by the grower-shipper, volume discounts, and other price adjustments and quality specifications. Changes in these marketing services coincided with the growth of value-added and consumer-branded products, increasing variety, consolidation of food wholesalers and retailers, the expansion of the foodservice sector, and the greater role of produce imports and year-round supply.

Fresh fruit and vegetable products move quickly through the supply chain to combat spoilage. After harvest, fresh produce is handled and packed either by a shipper or by grower-shipper. Produce grown in the United States may be exported, or sold direct to consumers, retail stores, or foodservice establishments. Sales from grower-shippers to retailers and foodservice establishments might be mediated by wholesalers or brokers, or might occur directly.

Protecting the safety of the U.S. food supply requires a comprehensive and coordinated effort throughout the food production and transportation/distribution system. The responsibility to safeguard our food supply is shared by everyone involved, from the grower to the consumer. This includes growers, farm workers, packers, shippers, transporters, importers, wholesalers, retailers, government agencies, and consumers.

The nation's farms, transportation and distribution systems, food processors, and retail food establishments are a vital part of our economy and are required for the nation's defense and health. Local, state, and federal food and agriculture regulatory agencies must work together with farmers, ranchers, food processors, food transportation companies and distributors, grocery stores, restaurants, and food workers to ensure food safety across the food continuum from source to point of service.

The FDA and U.S. Dept. of Agriculture (USDA) issued "Guidance for Industry—Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guidance document addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. This voluntary, science-based guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety and traceability of their produce.

Traceback is the ability to track food items, including fresh produce, back to their source (growers, packers, and so on). A system to identify the source of fresh produce cannot prevent the occurrence of a microbiological hazard that might lead to an initial outbreak of foodborne disease. However, the ability to identify the source of a product through traceback can serve as an important component of good agricultural and management practices intended to prevent the occurrence of food safety problems.

Improving FDA's ability to trace a contaminated product back to the source of production would allow the agency to conduct more rapid and thorough investigations. It would also allow producers to more precisely identify the source of a problem to improve production practices and could help narrow the scope of recalls by more quickly identifying the specific plant or country of origin. Reducing the time required before an intervention is used will better protect public health, help reduce the economic hardship affected industries face, and maintain consumer confidence in the U.S. food supply following an incident.

1.1 Scope of work as provided by FDA to IFT

This task order will be used to evaluate the relative public health, economic, and shock consequences (that is, risk) of traceability (product tracing) systems in the food and feed continuum for the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN), College Park, Maryland. An in-depth review of industry practices and various processing or engineering technologies, which may be used to track movement of food product, forward through the supply chain and trace food items back to the original source to increase FDA's ability to more rapidly and precisely track the origin and destination of contaminated food items will also be determined.

Independently and not as an agent of the Government, the IFT shall furnish the necessary personnel, materials, services, facilities, and otherwise do all things necessary for or incident to the performance of the work set forth herein.

IFT shall review the scientific literature, shall consult with experts, and shall consider the requirements of other governmental bodies to address the following:

1. IFT shall do an in-depth review of industry traceability systems and technologies that are currently being used as well as those that may be used in the near future in the United States as well as industry or government mandated traceability systems that are employed in overseas (international) markets. Particular attention shall be given to the breadth, depth, and precision of traceability systems that enable food and feed product to be linked from source to point of sale in the food continuum. The review will cover the continuum of food distribution from farm to table and will examine product tracing from points of service back to points of processing and production. Products and systems to be examined include processed products that may or may not have a label and lot number associated with them, as well as fresh products that may or may not have a label or lot number associated with them (that is, produce) as well as ingredients that may go into numerous or multiple finished products. Attention shall also be given to the accessibility of information by public health officials in food-related emergencies.

   Breadth: The amount of information the traceability system records.
   Depth: How far upstream or downstream in the supply chain the system tracks.
   Precision: The degree of assurance with which the system can pinpoint a particular product's movement or characteristics.
   Access: The speed with which track and trace information can be communicated to supply chain members and the speed with which requested information could be disseminated to public health officials during food-related emergencies.

2. IFT shall examine traceback methods that enable products in the food continuum to be linked from the point of sale back to the source. Particular attention shall be given to those links where dissimilar practices and technology are used in the food continuum (for example, incompatible data standards and paper-based systems compared with electronic systems).
3. IFT shall examine and complete an in-depth review of the costs associated with the industry traceability systems and technologies identified in item number 1 in the scope of work. These costs would include, but are not limited to: costs for capital equipment improvements, costs for additional recordkeeping that may be necessary, and costs for the harvesting and processing improvements to assist in the traceability systems. This examination will include how traceback can be accomplished rapidly from the point of service back to the point of production. (IFT note: this information is summarized in Volume 1 of this report and detailed in Volume 2.)
4. IFT shall provide a report (both hardcopy and electronic copy on diskette or CD-ROM in Microsoft Word compatible format and HTML format) of its evaluation of industry practices and technologies used for product tracing.
5. IFT shall provide a report (both hardcopy and electronic copy on diskette or CD-ROM in Microsoft Word compatible format and HTML format) of its examination and in.depth review of the costs associated with the industry traceability systems and technologies.
6. IFT shall provide recommendations for process improvements and technologies to more rapidly and precisely track and trace product in the food continuum.
7. IFT shall provide additional information on the suitability and feasibility of recommendations for use by large compared with very small business and barriers to implementation.

2.0 Background on Outbreaks

An effective product tracing system results in the protection of public health. Product tracing is very important to public health officials during their investigation to determine the source of a foodborne illness. Rapid and targeted product tracing provides both an identification of the implicated food and the prevention of further cases of illness. In this task, the Food and Drug Administration requested that the project focus on product tracing with an emphasis on preventing further consumption of contaminated product, as opposed to identifying the product associated with illness.

The following examples are provided to illustrate the complexities associated with tracking and tracing in different segments of the food supply chain, which have had a negative impact on public health.

2.1 Spinach outbreak 2006

Baby spinach was identified as the source of an *Escherichia coli* O157:H7 outbreak that resulted in 205 confirmed illnesses and 3 deaths. The 1st confirmed case of illness was reported on August 19, 2006 with the peak number of cases occurring on August 31, 2006; the number of cases trailed off in mid-September. Affected individuals reported consuming spinach prior to the illness linking this product to the illness. On September 13, 2006 epidemiologists in Wisconsin, New Mexico, and Oregon suspected fresh spinach was the source of small clusters in their states. At that time, the (Centers for Disease Control and Prevention) CDC's PulseNet confirmed the same pulsed field gel electrophoresis patterns among the patients in these states.

On September 14, FDA advised consumers by press releases and press conferences to not eat bagged fresh spinach. On September 15, a California company that produces bagged spinach under several brand names announced a recall of all fresh spinach-containing products with "best if used by" dates of August 17, 2006 to October 1, 2006. The firm had shipped product throughout the United States, Mexico, and Canada and as a precautionary measure, removed all lot codes that could possibly be in the market place. Since the product was branded, packaged, and had a lot code printed on the package, information on the specific product could be quickly communicated to enhance removal from the food distribution channels. The lot codes on the package allowed for the product to be traced back to a processor and production date and further facilitated identification of the grower.

The unique aspect of this investigation was that the product was one that was perishable and had a short shelf life. In fact, the product was at the end of the shelf life when it was recalled. It was a product that visually would indicate organoleptic unacceptability, although some consumers may continue to eat the product after the "best if used by" date. The product was easily traced to one supplier and identified by product type, brands, and lot codes, and was a single item.

2.2 Pet food recall

On March 15, 2007, the Canadian firm Menu Foods notified the FDA of a potential pet food problem that had been detected through consumer complaints and feeding trials. The firm's internal lot tracking information showed a change in an ingredient supply source from China. Menu Foods issued the first of 2 recalls on March 16, 2007, which included products under numerous brands that were distributed in Canada and the United States. On March 23, 2007, melamine was identified in the wheat gluten from China. On May 1, FDA found that melamine and cyanuric acid contamination together was linked to acute renal failure in pets. On September 21, 2007, FDA classified the Menu Foods recall as a Class I recall.

Menu Foods had the majority of the recalled products. However, 11 other pet food companies also conducted recalls due to the use in their manufacturing process of the same shipment of the wheat gluten imported from China. In addition to wheat gluten imported by ChemNutra, contaminated rice protein lots were also found. These contaminated ingredients resulted in reports of approximately 3600 pet deaths through a self-reporting system. The recall involved more than 100 brands of dog and cat food.

The unique aspects of this product trace forward were the overwhelming number of products affected and the dramatic psychological impact the recall had upon pet owners. While all the products recalled were pet food, the recall was so massive that it nearly emptied pet food supply display shelves and created concerns among owners as to what to feed pets. The product to trace forward was identified by type of product (dog or cat food), brand name and lot codes. These pet food recalls were nationwide with recalls announced during a 2- or 3-wk period. While the source of the contaminated ingredient was quickly identified, it took several weeks to pinpoint the agents involved in the contamination. The time required to investigate the unknown contamination added to consumer concerns. In this example, a contaminated imported ingredient was used by several different pet food manufacturers.

2.3 Peanut butter

In late 2006, there was a sudden increase in reports of *Salmonella* Tennessee infections with the number of cases doubling weekly. Extensive investigation in January and February of 2007 pinpointed 2 brands of peanut butter, both manufactured by the same plant. The outbreak identified 628 persons in 47 states infected with the outbreak strain of *Salmonella* Tennessee. On February 14, 2007, ConAgra Foods announced a recall of Peter Pan and Great Value peanut butter with a product code beginning with 2111, which identified the plant where the peanut butter was produced. The plant temporarily halted production. The outbreak had peaked prior to the recall and dropped suddenly following the recalls. It was nearly a month later before a positive test result was obtained from an unopened container of peanut butter.

A unique aspect of this recall was that the plant identification was part of the lot code which allowed the manufacturing facility to be quickly identified. Both branded products were manufactured at the same plant. Because the plant code was available on the consumer package, it was easy to track the product forward by brand and lot code information as the firm's recall included all lot codes. The food distribution system and consumers were well informed about what to look for and the appropriate action to be taken.

2.4 Peanut butter and peanut paste

In the fall of 2008, there was an increase in infections from *Salmonella* Typhimurium with the peak illnesses occurring in late December 2008. On January 9, 2009, the Minnesota Dept. of Agriculture reported a positive test result from an open institutional size container of peanut butter. On January 10, 2009, King Nut Co. issued a recall of the King Nut brand of peanut butter manufactured by a co-manufacturer, Peanut Corp. of America (PCA). On January 16, 2009, the Connecticut Dept. of Health found the outbreak strain in an unopened container of peanut butter. On this date, PCA expanded the recall to include peanut butter *and peanut paste* produced in their Georgia plant. On January 16, 2009, Kellogg Co. recalled Austin and Keebler brands of peanut butter crackers after confirming the use of PCA peanut paste. On January 28, 2009, PCA announced an expanded recall to include additional lots of product. On February 12, 2009 the State of Texas ordered the PCA plant in Texas to stop production and ordered all products produced since January 1, 2007 to be recalled.

On April 20, 2009, CDC announced that 714 persons in 46 states were infected by the peanut products traced to PCA. There were 9 deaths associated with the outbreak. There were about 500 product recalls over a 3-mo period involving nearly 4000 products. PCA produced less than 2% of the peanut butter/peanut paste available to the market. The impact upon the peanut industry is estimated to exceed $1 billion dollars.

The unique issues related to trace forward in this recall include the massive nature of the recall due to the product being used as an ingredient in numerous products under multiple brands. The PCA recall was also expanded 4 times in slightly more than a month. The trace forward was very difficult due to the many hands (brokers, formulators, distributors, and so on) that the product went through and the various products and brands involved in the recalls. The delay in recalls was also related to the product changing forms as an ingredient in various products. The communications flow within the industry may have slowed following the bankruptcy filing by PCA.

During the course of this task, IFT had an opportunity to speak with a peanut butter manufacturer who reported that during the course of 2 mo, the company experienced a 20% market decrease in sales of their brand, even though they did not receive any product from PCA. At 1 point, their call center received 4000 calls per day regarding the PCA issue.

2.5 Chili sauce

On July 7 and July 11, 2007, public health officials in Texas and Indiana reported to CDC 4 suspected cases of foodborne botulism. The 4 patients reported consuming Castleberry's hot dog chili sauce before the illness began. Containers from the 2 parties were retrieved and it was noted the products were produced on May 7 and 8 less than 5 h apart at the same plant. On July 18, 2007, FDA issued a consumer advisory and Castleberry Food Company issued a recall that included limited production dates of Castleberry's Hot Dog Chili Sauce Original, Castleberry's Austex Hot Dog Chili Sauce Original and Kroger Hot Dog Chili Sauce. On July 19, USDA-FSIS issued a press release on the meat.containing products that the firm produced. The firm expanded the recall on July 21 to include all product dates for 91 types of canned chili sauce, chili, other meat products, chicken products, and dog food that were manufactured in the same set of retorts. The plant produced chili sauces under 26 different brands. The products were shipped through the United States and Canada.

The unique aspects of this trace forward were the large number of brand names and the number of types of products involved along the extensive distribution chain. The use of the time in the lot codes on individual cans was a great aid in pinpointing the hour of production. Still, it was difficult to trace the product forward due to the vast number of products. Some stores may have multiple brands of the same product. The product is one having a long shelf life lending itself to storage in the home pantry.

3.0 Consumer Perceptions

An effective product tracing system provides more rapid resolution to a food contamination event, so that public confidence in the food supply is maintained, and disruption of commerce is limited. Consumer confidence in the U.S. and global food supply has decreased as a result of highly publicized food product recalls and other food scares in recent years, and appears to be fragile at best. Some notable and very public outbreaks include those highlighted previously. During this year, 2009, recalls resulting from contaminated peanut butter, pistachios, and sprouts have occurred, and more may occur before year's end. The global food supply has led to product recalls that are larger in size and may include many different types and brands of food products. Contaminated product may be widely distributed to different states and even multiple countries.

Consumer confidence in the food supply has faltered as many consumers now question where their food comes from and what is in it, among other considerations. A number of consumer confidence surveys have been conducted recently or consumer confidence questions have been added to annual consumer surveys. These surveys have all shown decreased consumer confidence in the food supply after product recalls (Food Processing 2007; Haberkorn 2007; Marler 2007). Improved product tracing is viewed by some as a measure to improve food safety, and therefore consumer confidence. Examples of recent consumer surveys and their results are described in more detail below.

The 4th Annual Intl. Food Information Council (IFIC) Food & Health Survey: Consumer Attitudes toward Food, Nutrition & Health polled a nationally representative sample of over 1060 Americans from February–March 2009. The online survey found that 49% of consumers polled were extremely or somewhat confident in the U.S. food supply. More than half of those polled felt that foodborne illness from bacteria was the most important food safety issue, while 30% felt that chemicals in food were an issue. Seventy-three percent believe food manufacturers are responsible for U.S. food safety, while 72% believe the government is responsible, followed by farmers/producers, retailers/foodservice, and lastly, consumers themselves. The survey found that few consumers appear to take food safety precautions when preparing and cooking food, and that most did not believe they had any obstacles to handling food safely. Consumers polled obtain information that guides their food and health practices primarily from the media, followed by the food label, family/friends, health professionals, grocery or other stores, product manufacturers, health associations, and lastly, from the government (IFIC 2009).

Results of the Food Marketing Institute's (FMI) Grocery Shopper Trends 2009: Economic Concerns Shaping How Consumers Shop, Cook and Dine, released in May 2009, show that consumers' confidence in the safety of supermarket food products was 83%, an increase from the 18-y low of 66% in 2007 and a slight increase compared to 2008. However, only 72% said they were "somewhat" confident. Consumer confidence in the safety of restaurant food was 68%. Nearly 90% of those polled agreed that they trust that fresh produce, canned and boxed foods, and meat, poultry, and fish sold by their grocery store are safe. Seventy-nine percent of those polled agreed that they trust the USDA to ensure that the food they purchase is safe, and 76% agreed with the same statement about the FDA. When food recalls are announced many consumers get their information from sources other than the government. Television was reported as the number one source for recall information, followed by the internet, newspapers or magazines, radio, friends or family members and lastly, government websites. Data for this survey were collected through surveys conducted by Harris Poll Online among a nationally representative sample of over 2000 U.S. shoppers (FMI Media 2009).

A food safety telephone survey of a nationally representative sample of over 1000 households was conducted by Consumer Reports Natl. Research Center. It found that the majority of consumers are concerned about the safety of imported foods, and would like the government to inspect the food supply more frequently and let the public know where food safety problems arise. Although 73% of consumers polled indicated that the current food supply is generally safe, the majority also indicated that their confidence in the food supply had decreased during the past several years. More than 60% of consumers polled were very concerned about harmful bacteria or chemicals in their food. Over 65% of consumers felt that FDA should inspect both foreign and domestic food facilities one or more times each month. Seventy-five percent of consumers strongly agreed that processed or packaged foods should be labeled with country of origin, and 73% strongly agreed that country-of-origin labeling should always be available at point of purchase. Over 80% of those polled strongly agreed that the government should be able to quickly and accurately trace food from production to sale, should require a recall when there are food safety issues, should disclose information about potentially harmful food such as origin and retailer location to consumers, and should disclose the names of public or private institutions that receive recalled meat. The survey was conducted in October 2008, and questions covered topics other than food safety, such as labeling claims, food additives, and shopping preferences (Greener Choices 2008).

A June 2009 Intl. Business Machines Corp. (IBM) study of 1000 consumers in the 10 largest U.S. cities showed that less than 20% of consumers trust food companies to develop and sell safe and healthy products, and that 60% are worried about the safety of their food. Eighty-three percent of those surveyed could name a food product that was recalled in the past 2 y due to contamination or other safety concerns, with almost half of those responses naming peanut butter and 15% naming spinach. Of those surveyed, almost half would be less likely to purchase a food again if it had been recalled due to contamination. Over 60% of those surveyed would not buy the food again until the source of contamination had been found and addressed. Eight percent would never purchase the food again, even after the source of contamination was found and addressed. Fifty-seven percent of those surveyed reported that they stopped purchasing certain foods within the past 2 y for safety reasons. Fifty-five percent of those surveyed trust food manufacturers to handle a recall, which is a decrease in consumer's level of trust over the past 2 y, and 72% said they trust their grocery store to properly handle recalls. Over 75% of those surveyed would like more information about the ingredients that make up food products, and more information about a product or its ingredients' origin(s). Seventy.four percent are interested in even more information, such as how the food is grown, processed, and manufactured (Camire and Spencer 2009).

4.0 Approach

Given the history of food safety events, impact on public health, and resulting decrease in consumer confidence of the food supply, IFT undertook, under contract with the U.S. Food and Drug

Administration (FDA), a study of traceability. As stated in the Task Order IFT received from FDA's Center for Food Safety and Applied Nutrition (CFSAN):

This task order will be used to evaluate the relative public health, economic and shock consequences (i.e., risk) of traceability systems in the food and feed continuum for FDA CFSAN, College Park, Maryland. An in-depth review of industry practices and various processing or engineering technologies, which may be used to track movement of food product, forward through the supply chain and trace food items back to the original source to increase FDA's ability to more rapidly and precisely track the origin and destination of contaminated food items will also be determined.

IFT assembled a 7-member "core expert panel" consisting of an agricultural economist, an epidemiologist, a representative from a nonprofit, international standards organization (GS1 US, promotes global standards organization [GS1] standards in the United States), a produce provider, a food industry safety and recall specialist, a food microbiologist, and our Senior Science Advisor, Dr. Frank Busta. The panel met face-to-face a total of 4 times throughout the year. During their 1st in-person meeting they deliberated the approach, identified key questions to ask members of the food industry, and suggested other industries that trace product that might be worth considering. During the 2nd in-person meeting, they reviewed the report and recommendations of the systems/technologies subpanel; reviewed discussions IFT staff had with food industry members; considered the outline proposed by the cost evaluation subpanel, and drafted recommendations on changes that would improve product tracing. During the 3rd meeting, they considered feedback from the food industry subpanel as well as the subpanel of state traceback investigators, and were able to draft final recommendations. They met a final time, along with members of each subpanel, to review the final draft reports.

The 4 subpanels that contributed to this task and the scope of their work was:

State Traceback Investigators: Determine the access of information given the current practices and processes employed by the food industry for product tracing, and compare that to the access if recommended changes in processes and practices were implemented.

Economists: Describe the types of costs and benefits related to product tracing based on the cost-related data collected from discussions with members of the food industry, and available literature that provides the basis for case studies.

Systems/Technologies: Consolidate and analyze discussions with "solution providers," assess advantages and disadvantages to issues such as standardization of information, medium used to communicate information, and technologies available for product tracing; identify infrastructure requirements for a select number of scenarios where different systems and technologies are used.

Food: Review discussions with food industry representatives to determine themes in practices and processes, particularly with respect to dissimilar practices; use the draft best practices generated by the core expert panel to identify barriers to implementation.

The names and affiliations of the core expert panel and subpanel contributors, as well as IFT staff involved in this task, are listed in Appendix A.

Prior to the 1st meeting of the core expert panel, IFT met with FDA to discuss details of the task. As a result of the meeting, IFT used the following assumptions for this task:

- The task should focus on tracing of fresh produce.
- Other industries (food and nonfood) should be explored for "best practices" as well as other systems or approaches that might have application in the food industry, specifically the fresh produce industry.
- In considering systems and components, IFT should assume that an epidemiological investigation was completed and contaminated food resulting in foodborne illness had already been identified.
- Systems and components suitable for "regulatory traceback" (paper or electronic documents including name, address, type of food, date received, lot information, and so on, presentable in a court of law) are desired.

Objective 1/Approach

IFT shall do an in-depth review of industry traceability systems and technologies that are currently being used as well as those that may be used in the near future in the United States as well as industry or government mandated traceability systems that are employed in overseas (international) markets. Particular attention shall be given to the breadth, depth, and precision of traceability systems that enable food and feed product to be linked from source to point of sale in the food continuum. The review will cover the continuum of food distribution from farm to table and will examine product tracing from points of service back to points of processing and production. Products and systems to be examined include processed or unprocessed products that may or may not have a label and lot number associated with them, as well as ingredients that may go into numerous or multiple finished products. Attention shall also be given to the accessibility of information by public health officials in food related emergencies.

Breadth: the amount of information the traceability system records

Depth: how far upstream or downstream in the supply chain the system tracks

Precision: the degree of assurance with which the system can pinpoint a particular product's movement or characteristics

Access: the speed with which track and trace information can be communicated to supply chain members and the speed with which requested information could be disseminated to public health officials during food related emergencies

IFT staff and on occasion, Dr. Busta or another member of the core expert panel, met or had a conference call, webinar, or in-person meeting with product tracing solution providers. Appendix B shows the format of the conversation flow. IFT also conducted a literature review of existing product tracing technologies and systems, including those that are in development and near commercialization. As indicated in section "Solution Systems," IFT spoke to representatives with expert knowledge of these systems to gain a clear understanding of the product tracing systems available to the food industry.

IFT staff spoke or met with representatives from several trade associations. Many of the trade associations have working groups or other efforts aimed at product tracing, discussed in more detail in section "Assessment of Current Industry Practices." IFT sought regular updates from these groups, and became familiar with many of the initiatives and their respective stages of development to better understand some of the information and comments that companies provided.

IFT held 58, 1-h conference calls with representatives of several food industry segments, and held additional calls with product tracing solutions providers, trade associations, and others.

Representatives from very small through large companies were included in the discussion. IFT spoke to 8 packaged goods companies, 4 ingredient companies, 4 animal feed representatives, 22 members of the produce industry (divided between growers, processors, distributors, and terminal/street markets), 3 nonproduce distributors, 7 representatives of the retail segment, and 10 representatives of the foodservice segment. Participants were solicited through a variety of mechanisms. IFT asked trade associations to make their members aware of the task and encourage participation. IFT also sought input through messages disseminated through the IFT Fruit and Vegetable Division listserv. In some cases, "solution providers" offered contacts of industry members. IFT staff relied heavily on personal contacts and contacts of the core expert panel. Interest in this task seemed to spread through "word of mouth" to a considerable extent. Later in the task, IFT sought out specific companies to fill any gaps in the portfolio of discussions.

The discussion agenda was very similar for each industry segment, but the flow and length of conversation depended on the product, size of the company, and many other factors. Many larger firms were able to provide information specific to their use of produce as well (for example, retailers and foodservice), or speak to ingredient tracing (for example, food processors).

IFT also researched product tracing in other industries, for example, airline, mail, automotive, steel, pharmaceuticals, and so on which is discussed in section "Traceability in Nonfood Industries."

To address access of information to public health officials, the core panel expert epidemiologist held conference calls with other state traceback experts. The form provided in Appendix C illustrates the specific questions asked of state traceback investigators to estimate the impact of various product tracing systems on the ability of public health personnel to conduct a rapid and thorough traceback.

Objective 2/Approach
IFT shall examine trace-back methods that enable products in the food continuum to be linked from the point of sale back to the source. Particular attention shall be given to those links where dissimilar practices and technology are used in the food continuum (for example incompatible data standards and paper-based systems versus electronic systems).

Early in the task, IFT began speaking to members of the food industry about their product tracing practices, using a discussion document developed with input from the core expert panel. The long version (used by IFT staff) is attached as Appendix D; and a shorter version, which was emailed to potential participants to provide an indication of the topics to be addressed, is included as Appendix E (note: this document was modified depending on the recipient, for example, a slightly different document was provided to those in retail compared with farmers).

IFT consolidated and analyzed the data to determine where dissimilar practices and technologies are used in the food continuum. The main areas of consideration were: type of information provided and captured (lot number and so on), standardization of information (for example, GS1 standard or other), and data storage method.

IFT used the services of the product trace expert on the core expert panel to assist us in the interpretation of data and detailed analysis of the systems and technologies commercially available. The systems, and differences in their acceptance and utilization, along with the challenges that dissimilar practices may or may not present, are documented in sections "Current Practices in the Food Industry" and "Overview of Existing and Emerging Systems."

Objective 3/ Approach
The contractor shall examine and complete an in-depth review of the costs associated with the industry traceability systems and technologies identified in item number 1 in the scope of work. These costs would include, but are not limited to: costs for capital equipment improvements, costs for additional recordkeeping that may be necessary, and costs for the harvesting and processing improvements to assist in the traceability systems.

One member of the core expert panel, Dr. Helen Jensen, helped develop discussion questions, which allowed the collection of data regarding the costs for capital equipment improvements, additional recordkeeping and costs for the harvesting and processing improvements to assist in the product tracing systems.

Once the data from cost-related questions were collected, we worked with Dr. Jensen on a consultancy basis to develop the initial estimate of the costs associated with the recommendations as proposed by the core expert panel. She led a subpanel to review the costs associated with the various product tracing systems and the cost to the industry (and perhaps, the cost to consumers) to implement the recommendations.

The impact on public health, the economy, and consumer shock decreases with a quick and accurate traceback. Case studies derived from existing literature and in.depth conversations with select members of the food industry provided examples of how costs and benefits associated with product tracing could be derived. Costs associated with various technologies were also developed. Key findings of the cost evaluation are presented in section "Cost–Benefit of Traceability," and the full report is included as Volume 2 of this report.

5.0 International Standards

5.1 Intergovernmental bodies

5.1.1 Codex. Traceability/product tracing is defined in the Codex Alimentarius Commission Procedural Manual (CAC 2008) as "the ability to follow the movement of a food through specified stages(s) of production, processing and distribution." The document, "Principles For Traceability/Product Tracing As A Tool Within A Food Inspection and Certification System," (CAC 2006) provides information to assist competent authorities in using traceability/product tracing to contribute to the protection of consumers against foodborne hazards and deceptive marketing practices and the facilitation of trade on the basis of accurate product descriptions. This document notes that product tracing does not in itself improve food safety outcomes unless it is combined with appropriate measures and requirements. However, it suggests that product tracing can contribute to the effectiveness and/or efficiency of associated food safety measures (for example, by providing information on suppliers or customers involved in potential food safety issues to enable targeted product recall/withdrawal). The document also states that a product tracing tool should be able to identify product at any specified stage of the food chain (from production to distribution), where the food came from (1-step back) and where the food went (1-step forward), as appropriate to the objectives of the food inspection and certification system. The document notes further that application of traceability/product tracing should take into account the capabilities of developing countries. If an importing country has objectives or outcomes of their food inspection and certification system that cannot be met by an exporting country, the importing country should consider the provision of assistance to the exporting country, especially in the case of a developing country.

More recently, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) produced and considered a discussion paper on "Development of Guidelines for Traceability/Product Tracing in the Context of Food Import and Export Inspection and Certification Systems" which analyzed information gathered by an electronic working group on countries' views and experiences with traceability. CCFICS determined that information was not sufficient to clearly identify gaps and specific needs in relation to implementation of product tracing and recommended to the Commission that the question of the need for further guidance be considered by the Food and Agriculture Organization/World Health Organization (FAO/WHO) Coordinating Committee (CCFICS 2008). The Commission endorsed this recommendation during its session in 2009 (CAC 2009).

5.1.2 OIE. The World Organization for Animal Health (OIE) helps its member countries and territories to implement animal identification and traceability systems to improve the effectiveness of their policies and activities relating to disease prevention and control, animal production food safety, and certification of exports. OIE has addressed animal identification and product tracing for a number of years. Identification and product tracing guidelines/standards were established in May 2007. These standards define animal identification as the combination of the identification and registration of an animal individually, with a unique identifier, or collectively by its epidemiological unit or group, with a unique group identifier. Animal traceability is defined as the ability to follow an animal or group of animals during all stages of life. The OIE Terrestrial Animal Health Code has a chapter, adopted in 2008, that addresses the development and implementation of identification systems to achieve animal traceability (OIE 2009b). Aspects of the Code relating to animal identification are listed in the following box.

Select aspects of the OIE Terrestrial Animal Health Code relating to animal identification and traceability include:

Various factors that may determine the system chosen for animal identification and traceability include outcomes of risk assessment, the animal and public health situation, animal population parameters (for example, species, numbers, and distribution), types of production, animal movement patterns, available technologies, trade in animals and animal products, cost/benefit analysis and other economic, geographical and environmental considerations, and cultural aspects.

The choice of a physical animal identifier should consider elements such as the durability, human resources, species and age of the animals to be identified, required period of identification, cultural aspects, animal welfare, technology, compatibility and relevant standards, farming practices, production systems, animal population, climatic conditions, resistance to tampering, trade considerations, cost, and retention and readability of the identification methods.

The information system should be designed according to the scope, performance criteria and desired outcomes, may be paper based or electronic, and should provide for the collection, compilation, storage, and retrieval of information on matters relevant to registration.

Animal identification should be recorded on documents accompanying samples collected for analysis.

Components of the animal identification system operating within abattoirs should complement and be compatible with arrangements for tracking animal products through the food chain and identification should be maintained during the processing of the carcass until it is deemed fit for human consumption.

OIE held a conference in Argentina in 2009 (OIE 2009a) that led to a number of recommendations for its members (OIE 2009c) which are shown in the box below.

Take steps to ensure that all parties in the food production chain are aware, as appropriate, of the OIE and Codex standards and promote their implementation in partnership with the private sector.

Establish a clear regulatory framework for animal identification and traceability, including requirements for enforcement; coordination; data management, ownership, confidentiality, and access; technical and, at least initially, financial support.

Address concerns that animal identification and traceability programs may be used for the purpose of collecting or raising tax revenues, because this could discourage the national adoption of such programs and jeopardize the global improvement of public and animal health.

Support the development of education and scientific research programs relevant to animal identification and traceability for key players in the food production chain, particularly veterinarians, livestock owners and industry operators.

Encourage the private sector to respect the official standards of the OIE and Codex Alimentarius Commission and not promote private standards that could conflict with those of OIE and Codex nor impose unjustified requirements.

Continue to recommend animal identification and traceability programs that are compatible within a specific country for each animal species, simple, affordable, outcomes based, transparent, auditable and commensurate with the size and nature of the farming sector in each country and based on a scientific assessment of animal and public health risks. Consumer requests and needs and the results of cost benefit assessment also need to be taken into account.

In collaboration with key partners, such as FAO and regional organizations, provide members appropriate capacity building for the use of the OIE standards, including the provision of inputs relevant to veterinary education on animal health and animal production food safety.

Continue to develop arguments convincing donors and international organizations to commit to economic development and help Veterinary Services and their partners in developing countries implement the OIE standards for the identification and traceability of animals and animal products.

Promote the development of OIE Collaborating Centers on animal identification and traceability that could build and manage a global database of different national approaches and provide advice to developing countries in the implementation of programs.

5.2 Commercial Standards

5.2.1 Intl. Organization for Standardization (ISO). Within the ISO 9000 series for Quality Management Systems: the ISO 9001:2008 standard requirement for identification and product tracing states (a) that "Where appropriate, the organization shall identify the product by suitable means throughout product realization and where traceability is a requirement, the organization shall control the unique identification of the product and maintain records" (Campden BRI 2009); and (b) preservation of product states that "As applicable, preservation shall include identification" and that "Preservation shall also apply to the constituent parts of a product" (Campden BRI 2009). In ISO 22000:2005, which specifies requirements for a food safety management system, there is a requirement which addresses the establishment and application of a product tracing system "that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records" (Campden BRI 2009). ISO 22005:2007 gives the principles and specifies basic requirements for the design and implementation of a food and feed traceability system. It does not specify how product tracing should be achieved but requires that the organization should define the information to be obtained from suppliers, to be collected concerning the product and processing history, and to be provided to its customers and/or suppliers (Campden BRI 2009).

A report (Chartier and Van Den Akker 2008) emanating from the Global Radio Frequency Identification (RFID) Interoperability Forum for Standards (GRIFS; see text below for more detail) on the state of the art of RFID points to additional RFID-pertinent ISO standards:

ISO/IEC 15961 series for commands, responses and application related data,
ISO/IEC 15962 for data encoding and decoding,
ISO/IEC 24791-2 for data management,
ISO/IEC 24791-5 for relevant aspects of device interface,
ISO/IEC 15459 series for unique identifiers,
ISO/IEC 15418 which points to the 2 major data dictionaries used in bar code applications, and
ISO/IEC 15434 which defines a message structure which is highly suitable for a "read all" type of data capture environment

5.2.2 GS1. GS1 is a neutral not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply chains. GS1 is driven by more than a million companies, who execute more than 6 billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 108 countries; the Global Office is in Brussels, Belgium.

The U.S. affiliate of GS1, GS1 US, is a not-for-profit organization dedicated to the adoption and implementation of standards-based, global supply-chain solutions. More than 200000 businesses in 25 industries rely on GS1 US for trading-partner collaboration and for maximizing the cost effectiveness, speed, visibility, and traceability of their goods moving around the world. They achieve these benefits through GS1 US solutions based on GS1 global unique-numbering and identification systems, bar codes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code (UNSPSC®, standardized naming of products through 4-level taxonomy) for the UNDP (GS1 US 2009a).

GS1 has defined product tracing as a business process and produced the GS1 Global Traceability Standard (GS1 US 2009b), which links it to enabling technologies and relevant GS1 System tools. GS1 has a large number of traceability-related activities ongoing around the world, examples of which are provided in Appendix F.

The GS1 standard: (a) addresses the entire supply chain and can be applied to any product; (b) is based on practices used in over 150 countries by a large majority of supply chain partners; (c) describes the creation of accurate records of transactions; (d) meets the core legislative and business need to cost-effectively trace back (1-step down) and track forward (1-step up) at any point along the length of the supply chain, no matter how many trading partners, business process steps, national, and international borders are involved; and (e) is compatible with ISO standard 2005 for product tracing.

The GS1 standards enabling implementation of the GS1 Traceability Standard are: Global Trade Item Number (GTIN), Global Location Number (GLN), Serial Shipping Container Code (SSCC), GS1-128 Bar code, Reduced Space Symbology (RSS), Data Matrix, Electronic Product Code (EPC), Global Data Dictionary (GDD), GS1 SML, and European Article Number (EAN)COM 3-business messages (Align and Deliver), General GS1 Specifications, and Global Product Classification (GPC).

The GS1 System of integrated standards includes:

Bar codes: global standards for automatic identification; providing rapid and accurate, item, asset, or location identification;
E Com: global standards for electronic business messaging; providing rapid, efficient, and accurate business data exchange;
GDSN: the environment for global data synchronization; providing standardized, reliable data for effective business transactions;
EPCglobal: global standards for RFID-based identification; providing more accurate, immediate and cost-effective visibility of information;
GS1 Traceability: a robust solution for tracking and tracing items through the supply chain (GS1 US 2009c).

By joining GS1, a company can receive, for a fee, a prefix that uniquely identifies the company for supply chain and electronic commerce applications. GS1 also promotes the use of the GTIN to uniquely identify trade items. This procedure has been adopted and encouraged by many programs and guidelines to support product tracing. A company can register with GS1 and receive their own company prefix identification number that can be used with bar codes, RFID tags and electronic commerce. GS1 standards enable use of standardized bar code formats that will be recognized throughout upstream and downstream supply chains. Information can be easily communicated from company to company with processes and software utilizing the GS1 standards. The GS1 System is an open system; a company does not have to be a GS1 Member to scan and read bar codes based on the GS1 Standards.

GS1 has launched a work group to produce an implementation guideline that can be used by any company implementing product tracing practices in the fruit and vegetable (produce) supply chain anywhere in the world. The guidelines will identify best implementation practices and will be based on existing GS1 standards (GS1 US 2009d, 2009e).

5.2.3 GlobalGAP. A GlobalGAP standard applies to the primary production sector (crops, livestock, and aquaculture), covers an increasing number of individual products from fruit and vegetables to salmon and trout, and has traceability-related control points (for example, the Crops Base module requires that GlobalGAP registered product is traceable back to and traceable from the registered farm where it has been grown) (Campden BRI 2009). GlobalGAP (formerly EurepGAP) is a private sector body that sets voluntary standards for certification of agricultural products around the globe, including aquaculture (GlobalGAP 2009). The organization is a partnership of producers and retailers that want to establish certification standards and procedures for good agricultural practices, based on EN45011 or ISO/IEC Guide 65 and having the objective verify good practices along the whole production chain. Global GAP certification is conducted by more than 100 organizations in more than 80 countries. EurepGAP was initiated in 1997 by retailers involved in the Euro-Retailer Produce Working Group, with British retailers and supermarkets in continental Europe as the driving forces, responding to consumer concern about product safety and environmental and labor standards. GlobalGAP members include retail and foodservice members, producers, suppliers, and associate members from the input and service side of agriculture. It has member product bases ranging from crops to livestock and aquaculture to compound feed and plant propagation material. Recognizing the structural difficulties faced by small-scale farmers, GlobalGAP implemented group certification, smallholder manual, and feedback opportunities to facilitate market access for small-scale farmers (GlobalGAP 2009).

5.2.4 SQF program code and guidance. The 3-level SQF 2000 code, a global food safety and quality certification program and management system, is within the Safe Quality Food (SQF) Program. It is a HACCP-based supplier assurance code for the food manufacturing and distributing industries, which addresses, among other things, product identification, trace, withdrawal, and recall (SQF Inst. 2009). The Product Identification provision requires that the methods and responsibility for identifying product during all stages of production and storage be documented and implemented. The product identification system is implemented to ensure that (a) product is clearly identifiable during all stages of receipt, production, storage, and dispatch and (b) finished product is labeled to the customer specification and/or regulatory requirements and product identification records be maintained. The Product Trace provision requires that: finished product be traceable to the customer (one up); product tracing be provided through the process to raw materials, food contact packaging and materials, and other inputs (one back); product tracing is maintained where product is reworked; the effectiveness of the product trace system be tested at least annually; and records of product dispatch and destination be maintained. SQF was launched in 1994 in Australia and since 2004 has been administered by the SQF Inst., a division of the Food Marketing Inst., an association that conducts programs in public affairs, food safety, research, education, and industry relations on behalf of its 1500 member companies in the United States and around the world.

5.3 Regulations and activities in specific regions and countries

Select examples and highlights of traceability-related regulations and activities in a number of countries are provided below, by region. Details on product tracing interests and resources (including regulations), by commodity, country, type of information, and information source are accessible through the Intl. Portal on Food Safety, Animal and Plant Health (IPFSAPH 2009).

5.3.1 Asia. IBM, food software company FXA Group, and 2 Vietnamese seafood producers (Vietnam Assn. of Seafood Exporters and Producers and the Vietnamese State Agency for Technological Innovation [SATI]) are collaborating to improve seafood safety through greater product tracing via RFID to track exports (Decision News Media SAS 2009). Through this collaboration, product trace technologies will be tested at selected Vietnamese farms that export seafood to retailers in Japan, the United States, and Europe. Data will be collected on originating farms, where the seafood is processed, current location, and temperature, along with other data, and made accessible throughout the supply chain including wholesalers, shippers, and retailers. RFIDNews reported (RFID News 2009) that through this project SATI hoped to replicate the success of a similar system in Thailand.

The Ministry of Agriculture, Forestry and Fisheries of Japan issued "Guidelines for Introduction of Food Traceability Systems and Case Study of Traceability System" in 2003 (Matsuda 2009). The fundamentals of the guidelines state that food business operators at each stage of the food chain should at least identify food products, raw materials, suppliers and purchasers, correlate them with each other, and record and store this information.

Lee (2007) described product tracing in Korea, which implemented legal measures for introducing product tracing for agri-products, focusing on production and packaging, with the Agricultural Products Quality Control Act in 2005. The Act defines product tracing as "recording and maintaining information from production to the sales stages so that when problems arise in reliability of the corresponding agricultural product, the causes can be traced and necessary measures can be taken." Product tracing was made mandatory for good agricultural practice agriproducts. Lee reported that paper and 1-dimensional bar codes were used for product information, and that new models, such as RFID, were being developed.

Hu (2009) reported on the development of Good Agriculture Practice (GAP) and product tracing in Taiwan. Hu reported that the Taiwan Agricultural Products Traceability System trial plan was developed in 2004, and that the system is a combination of HACCP, GAP, legal system standard, 3rd-party audit system, certification logos, information technology-based management, and product tracing system which covers farming to food processing, packaging, distribution, and marketing to consumers. The Agricultural Products and Certification Act, promulgated in 2007, addressed product tracing, defining it and establishing that the central competent authority may implement a voluntary product tracing certification system, and when necessary, may announce the items and scope of specific products for compulsory traceability certification. The Act also established that the agricultural product operator who claims traceability shall provide product tracing information including the product name, the agricultural product operator's name, the production site, the tracing code, the main operational item, the packing date, the certification body's name and the term of certification validity, and shall maintain such data for a certain period of time as prescribed by the central competent authority. Also, the product tracing log is to be preserved at least 1 y after the expiration of availability date. Since the promulgation of the Act, Hu reported that 8 subregulations have been stipulated.

5.3.2 Eastern Mediterranean. Jordan has established a framework for a complete product tracing system after its selection into the World Trade Organization in April 2000. Prior to this date, Jordan exhausted all resources testing 100% of food imports while keeping no records of the data, risk assessments or performing any sort of tracing or tracking of outbreaks. Currently, Jordan is utilizing the region's 1st electronic national database of imports to track and investigate product and disease movement (FAO/WHO 2004).

5.3.3 Africa. This region differs slightly in its approach to food traceability and food safety policy. At the African Food Safety and Traceability Conference which took place in April of 2007, current status and future goals for national and regional traceability were discussed. Although they were considered important, the consensus was that because "Africa still faces food security issues food traceability may not be viewed as a top priority" (African Food Safety and Traceability Conference 2007). Thus, product tracing is not generally a large effort in this region until concern arises from, for example, a specific disease occurrence. Numerous nations simply do not have existing food legislation, let alone traceability standards. Others still have food laws from their colonial authorities, which place little importance on the citizens' health and may be obsolete. Multiple food authorities further complicate food policy in the region.

5.3.4 Europe. Under the framework of the General Food Law, EC Regulation Nr 178/2002, product tracing is defined as "The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution," with "stages of production, processing and distribution" meaning "any stage, including import, from and including primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed." The legal framework for product tracing in the European Union (EU), as described in Articles 18, 19, and 20 of the law, requires food and feed businesses, as of January 1, 2005 to identify from whom and to whom a food, feed, or food-producing animal or any substance intended to be or expected to be incorporated into a food or feed (that is, product) has been supplied. Also systems and procedures are to be in place to allow for this information to be made available to the competent authorities on demand. Businesses need to adequately label or identify their product to facilitate its tracing, through relevant documentation or information in accordance with the relevant requirements of more specific provisions. In instances in which product compliance with food safety requirements is in question, procedures to withdraw the product from the market or consumers is to be initiated immediately and the competent authorities or consumers are to be informed of the reason for the withdrawal. The EU legislation does not, however, require internal product tracing, that is, the matching up of all inputs to outputs, which is a feature of international and commercial standards (Campden BRI 2009).

The EU legal requirements apply to any business that trades food at all stages of the food chain, including primary producers, manufacturers, wholesalers, retailers, transporters, distributors, and those dealing in the purchase and sale of bulk commodities, even if their supplier is not within the EU, but they do not extend to suppliers in developing countries (Campden BRI 2009). Live "food-producing animals" are subject to the traceability requirements only if they go directly into a food product; similarly, seeds that do not directly go into a food product, such as when they are used to produce crops in primary production, are not subject to the traceability requirements (Campden BRI 2009). Additionally, nonfood materials used in primary production, such as pesticides, veterinary medicines, and fertilizers, are not subject to the traceability requirements; however, primary producers are required to identify the suppliers of the products used in the production of crops or food-producing animals (Campden BRI 2009). Individual member states are charged with oversight to ensure the most complete food chain safety, often including the duties of testing, surveillance, and enforcement through inspections. As in the United States, the EU's import policy holds that the country of origin must uphold its goods to the EU standard.

The EU has published guidelines that require business operators to document the names and addresses of their suppliers and customers in each case, as well as the nature of the product and date of delivery. The guidelines also encourage operators to keep information on the volume or quantity of a product, the batch number if there is one, and a more detailed description of the product, such as raw or processed (European Commission, 2007a, 2007c). In addition, sector-specific legislation applies to certain categories of food products (fruit and vegetables, beef, fish, honey, olive oil), to enable consumers to identify their origin and authenticity. Further, food animals must be tagged with information on their origin, date taken to slaughter, and be stamped with the traceability code of the abattoir (European Commission 2007c). There are special traceability rules for tracing and labeling genetically modified product content.

Not all EU regulations have been implemented at a national level throughout the European Union. In a survey by WHO, only 16 of the 23 EU member states in the United Nations (UN) World Health Organization stated that they possess "administrative structures for implementing food and nutrition strategies" (Comparative analysis of food and nutrition policies in the WHO European Member States 2003). Albania has just prepared a new draft Law on Food and it is being debated in their parliament. This law does not cover all the standards of the EU, namely, EC Regulation Nr 178/2002, and is missing information on issues such as traceability, the precautionary principle, and the significance of industry observance (Consultation on the Improvement of Food Control System in Albania 2008).

An integrated web-based veterinary system, Trade Control and Expert System (TRACES), maintained by the EC Health and Consumer Protection Directorate General, was established in 2004 by Commission Decision 2004/292/EC to enable traceability of animals across borders, establishing a central database for tracking the movement of animals within the EU and from other countries so that in the event of a disease outbreak potentially affected animals can be quickly identified and appropriate action taken (European Commission 2007b). Through TRACES, movement of live animals, animal products, and germplasm within the EU are also monitored, so that traders can be provided with the equivalent certificates. The technical functionalities and approach included: development of a central database, workflow, and web interface; e-mail notifications; development of system-to-system connections between TRACES and the member states applications; and application of TEMPO, EC/Directorate General for Health & Consumer Protection (SANCO) standard development tools and architecture guidelines.

Two systems are established to aid in traceability and limit the damage an outbreak can cause by providing easy access to initial information at the notice of a contamination occurrence. The first is the Rapid Alert System for Food and Feed (RASFF) which quickly disseminates information regarding new health risks by sending out a message from individual nations. Any involved governments are notified on this system and begin tracing and tracking to reach both the source of the problem and the exposed customers. The 2nd system is the EU Program on Monitoring and Assessment of Potentially Hazardous Substances (GEMS/Food-EURO) established by the World Health Organization which also aims to establish a complete connection for the flow of prevention and crisis information aiding especially in the traceability of a multi-nation contamination.

Examples of EU funded projects include the 5-y TRACE project, which began in 2005, and FoodTrace, which began in 2002 (European Commission 2007c). The TRACE project, supported by more than 50 European organizations and one from China, aims to deliver integrated traceability systems, guides to traceability best practice, and food verification systems, specifically in the mineral water, chicken, meat, honey, and cereal sectors (TRACE 2009). Also through TRACE funding, a TraceFood Wiki (TraceFood Wiki 2009) exists for assisting traceability implementation. In the TraceFood Wiki, participants may access "Recommendations for Good Traceability Practice [GTP] in the Food Industry," with generic GTP (for implementing internal traceability, chain traceability, and adapting electronic exchange of traceability information) and sector specific GTP (for seafood, mineral water, honey, and chicken). FoodTrace is designed to enhance traceability procedures between businesses, seeking to establish a clear identification system and a network of databases so that information can be centralized and shared (FoodTrace 2009). The generic framework for FoodTrace is accessible at http://www.eufoodtrace.org/framework/.

An international forum was organized to focus and disseminate the results of European Commission's investment in research on food traceability. It is a project supported by the EC's 6th Framework Programme known as PETER (Promoting European Traceability Excellence & Research (PETER 2009). The stated purpose of PETER is "to harmonise the points of common interest, tools, content, and strategies of several research programmes through the involvement of their coordinators. In addition, it will consider previous and new programmes on traceability." The final conference of this project was held in 2008; however, the web materials seem current. Since this program and some of its offshoots seek to provide international standards for traceability, FDA and other federal regulatory agencies may want to consider further engagement with PETER.

A Global RFID Interoperability Forum for Standards (GRIFS; the Forum), a Support Action Project funded by the European Commission's 7th Framework Programme and coordinated by GS1, the European Telecommunications Standards Inst. (ETSI), and the European Committee for Standardization (CEN) was initiated in January 2008. GRIFS is a 2-y project to improve collaboration and maximize the global interoperability of RFID standards (GRIFS 2009). Associated partners include GS1 member organizations from Poland, the United Kingdom, South Africa, Russia, United States, Brazil, China, Hong Kong, India, Japan, Korea, and Singapore. Details on the kickoff meeting held in Washington, D.C. June 30–July 1, 2009 and the launch of an online database of international RFID standards announced May 7, 2009 are accessible online (GRIFS 2009). At the meeting, speakers highlighted the need for a neutral forum where standards bodies would have the opportunity to share information and develop synergies, thus reducing overlap and possible contradictions in work plans. Mr. Gerald Santucci, Head of Unit Networked Enterprise & Radio Frequency Identification, DG Information Society and Media, European Commission issued a statement which included mention of the European Commission being willing to promote the interoperability of RFID standards across national and regional boundaries as well as across different economic standards. The database of RFID standards summarizes all current international RFID standards, whether published or in development; allows a search by areas of applications, standards, organizations, or status; contains information about 163 standards listed; and will be updated and open to comments by registered users. GRIFS partners are also publishing a Memorandum of Understanding (MOU) to support the organization of the Global Forum of Collaboration on RFID standardization, anticipating that major international standardization bodies active in RFID will sign it and use the Forum to collaborate with peers. Four meetings of the Forum will be organized in Asia, America, and Europe in the coming year. The MOU will be finalized during the final meeting in Europe. A 97-page GRIFS RFID standardization state-of-the-art report is accessible on their website (Chartier and Van Den Akker 2008).

Also within the EU 7th Framework Programme is the "CASAGRAS partnership" involving organizations from China, Japan, Korea, and the United States to address global RFID-related standardization. The partners met in China in November, 2008 and agreed on a vision statement and definition for the "Internet of Things" (CASAGRAS 2008). Participants critiqued 7 white papers and agreed on a "global network infrastructure, linking physical and virtual objects through the exploitation of data capture and communications capabilities." They also agreed that global coding would be one of the most important considerations and challenges within the CASAGRAS project. The final CASAGRAS project report was expected to be presented in June 2009 (CASAGRAS 2008).

The British Retail Consortium (BRC) addresses traceability in its Global Standard for Food Safety Issue 5, 1 of 4 of its Technical Standards, and in a Best Practice Guideline. The fundamental requirement in the Global Standard for Food Safety Issue 5 is "the company shall have a system to identify and trace product lots and follow this through all raw materials (including primary and any other relevant packaging materials and processing aids), all stages of processing and the distribution of the finished product to the customer in a timely manner" (BRC Global Standards 2009a). The specific requirements of this standard are:

- The identification of raw materials, including primary and any other relevant packaging and processing aids, work-in-progress, partially used materials, finished products and materials pending investigation shall be adequate to ensure traceability.
- The company shall test the traceability systems to ensure that traceability can be determined from raw material to the first level of distribution of the finished product and back. The amount of incoming raw material shall be reconciled against the amount used in the resulting finished products, also taking into account process waste and rework. This shall occur at a predetermined frequency and results shall be retained for inspection. The test shall take place at least annually.
- Where there is a requirement to ensure identity preservation within the supply chain, for example, to use a logo or to make a claim to a product characteristic or attribute, appropriate controls and testing procedures shall be in place.
- Where rework or any reworking operation is performed, traceability shall be maintained. In addition, the company must be able to demonstrate that this does not affect the safety, regulatory, or legal status of the finished product, for example, ingredient declaration, allergy information or identity preservation, nutritional labeling as required by regulation.

The BRC Best Practice Guideline: Traceability—Issue 2 (BRC Global Standards 2009b) addresses requirements for traceability, principles of an effective traceability system, how to undertake a traceability test. BRC Practice Guideline also identifies opportunities for improvements and sources of further information when developing traceability technology, to ensure that problems within the manufacturing process can be effectively identified and managed. The BRC states that the BRC Global Standards were originally developed in response to the needs of U.K. members of the British Retail Consortium, but have gained usage worldwide. According to BRC's website their standards are now specified by growing numbers of retailers and branded manufacturers in the EU, North America and elsewhere; and more than 14000 companies operating in more than 90 countries have achieved certification against one of the Global Standards.

The Intl. Food Standard (IFS 2003a) is a quality assurance and food safety standard developed by members of the German retail federation for retailer- and wholesaler-branded food products to enable the assessment of suppliers' food safety and quality systems, generally applicable for the entire food supply chain excluding the pre-farm-sector. Traceability requirements are addressed in the storage and distribution requirements section of the IFS (IFS 2003b). The IFS is endorsed by the Global Food Safety Initiative and has support from retailers from Austria, Poland, Spain, and Switzerland. Retailers and wholesalers taking part in the HDE (Hauptverband des Deutschen Einzelhandels) Committee for Food Law and Quality Assurance, the FCD (Federation des Entreprises du Commerce et de la Distribution) Quality Committee, in the Federdistribuzione Quality Committee, COOP, and CONAD support the IFS and require an IFS certification from their suppliers (IFS 2003c). IFS certification bodies have regional offices in Canada, United States, Mexico, Ecuador, Chile, Brazil, South Africa, Turkey, Egypt, Israel, India, Russia, China, Hong Kong, Thailand, and Malaysia.

Campden BRI, a U.K.-based research and development organization of food and drink manufacturers, produced in 2009 Guideline Nr 60—"Traceability in the food and feed chain: General Principles and basic system requirements" (Campden BRI 2009). The guideline addresses how to set up and conduct a traceability study, planning stages to enable traceability, how to establish and implement traceability, and examples of traceability plans.

In Norway, Matiq, the information technology subsidiary Nortura, Norway's largest food supplier, and IBM signed an agreement in 2008 to use RFID technology to track and trace poultry and meat products from the farm, through the supply chain, to supermarket shelves (IBM 2008a). Product packaging is to be tagged with RFID chips to help ensure that products are kept in optimal conditions. The software is to comply with GS1 EPCglobal's Electronic Product Code Information Services (EPCIS) standard. At the core of the system is IBM's WebSphere RFID Information Center, which provides software for enterprises seeking to share product movement information with trading partners that are also using EPCIS compliant solutions (IBM 2008b).

Following the incident of dioxin contamination identified in pork fat and animal feed supplies in December 2008 in Ireland, the Joint Committee on Agriculture, Fisheries and Food held a meeting and a series of hearings to examine the impact and consequences of the contamination and effectiveness of the traceability system (Houses of the Oireachtas 2009). The report of findings, issued May 2009, indicated that the present system for monitoring and tracing Irish pork products is ineffective and significant changes are required to avoid a repeat of the total recall of Irish pork products. It was also reported that an effective traceability system would have facilitated a recall of only contaminated product, which amounts to 10% of the produce that had to be recalled.

5.3.5 Western Pacific. *Australia.* In Australia, Stock Identification Regulation 2005 (State of Queensland 2005), as amended on or before March 15, 2008, mainly intended to help prevent, control, and eradicate disease by "giving effect to the system known as the 'national livestock identification system.' " This achieved principally by requirements that create the capacity to trace livestock movement. The secondary purpose of the regulation is to help to identify the status and stock of chemical residue, disease or hormonal growth promotant (HGP) of holdings and other particular premises, and, potentially, of downstream animal products from the stock. In this regulation, the chief inspector is required to keep a register of registered premises (determined on the basis of having a threshold number or greater of designated registerable stock), for which a unique property identification code, owner name, name of registered premise if one exists, address and locality, and the status of any chemical residue, disease, or HGP must be included. Tagging (for example, permanent breeder tags, temporary transaction and saleyard tags) is involved in designated stock that are transported, with requirements for different types of approved tags and their use.

Additionally, Food Production (Safety) Regulation 2002 requires accreditation holders who process meat and smallgoods to keep records containing details on the name or number of the accreditation holder where the meat originates, batch identification, batch processor identification, date of batch processing, and identification of any other accreditation holder from whom other meat or smallgoods in the batch is derived, and any other information pertinent for recall purposes (State of Queensland 2009).

New Zealand. Code of Practice for the Cold and Dry Stores addresses traceability and inventory control, requiring all operators of risk management programs, all exporters, and others to have a tracking system that allows for the identification and records maintenance of animal material and animal product. The code enables the tracing of the movement of the animal material and product from supplier and operator premises to the next recipient of the animal material or product. It also provides for risk management programs relating to storing or transporting dairy material, maintenance of records for all dairy material processed indicating the source of the dairy material, when it was received, destination of the dairy material, and when it left or was delivered. Food (Importer General Requirements) Standards 2008, as described in guidance (NZFSA 2008) address for recall purposes traceability records on imported food sources. Importers must hold relevant product information such as specifications, lists of ingredients, and traceability information including product code, brand name, and common name for product, container size, lot identification, batch code, and date marking. Key information about how the product got from point of purchase to New Zealand (including port of dispatch, port of entry, carriers, and import broker) is expected to be readily available for recall purposes. Purchase records are expected to include quantity of food imported in each transaction/consignment, product code or other traceability information such as product name and batch code or date marking, and date of purchase from supplier, wholesaler, or manufacturer.

A "Generic Element" entitled "Draft Identification and Traceability" and noting "Guidance for Developing Good Operating Practice Procedures" dated February 2009 that is available on the New Zealand Food Safety Authority's web site (NZFSA 2009a) indicates that food identification requirements are described under Standards 1.1.1, 1.2.2, and 1.2.5 of the Australia New Zealand Food Standards Code and provides guidance relating to identification and traceability. The document mentions the purpose/scope of ensuring incoming materials and products are "traceable both forward (to your immediate customers) and backwards (to your suppliers)" (NZFSA 2009b). Another document available at the NZFSA web site that mentions traceability is the "Apiarist and Beekeeper Statement for the Harvest of Honey and Other Bee Products for Human Consumption" form (NZFSA 2009c), effective July 2009, which is for "providing information to support fitness for human consumption, product traceability and suitability, in accordance with Food Act 1981 and the Animal Products Act 1999." The form captures apiarist identification details, and product type, quantity, and code number, as well as apiary registration number, harvest date, and certain hive operation details.

5.3.6 North America. In Canada, the Food and Drug Act is the main piece of legislation for food safety and traceability; Health Canada is responsible for establishing the standards, while the Canadian Food Inspection Agency is responsible for the enforcement and inspections necessary for the observance of the Act. Canada shares jurisdiction over food and health policy between national, provincial, territorial, and local authorities and as such needs a clear outline of responsibilities for all levels of authority like the "Foodborne Illness Outbreak Response Protocol" (PAHO 2009). The new Food and Consumer Product Safety Action Plan is a current review to update policy and "strengthen health, consumer and food products" (GAO 2008).

With respect to animal identification, regulated programs exist for the beef cattle, dairy cattle, bison, and sheep sectors (Canadian Food Inspection Agency 2008). The Canadian Cattle Identification Program introduced in 2001 and the Canadian Sheep Identification Program introduced in 2004, mandatory in all provinces, require all bovine, bison, and ovine animals to bear a registered identification (ID) tag before leaving the farm of origin. Information on cattle, bison, and sheep from most provinces is stored in a central database maintained by the Canadian Cattle Identification Agency, with the exception of Quebec, where the information is stored in a database maintained by Agri-Tracabilite Quebec. The import and export of cattle, bison and sheep must be reported to a traceability database, and abattoirs must report the death or slaughter of cattle and bison. Canadian agriculture ministers and industries are developing and phasing-in a Natl. Agriculture and Food Traceability System, which is being initiated with livestock and poultry.

Agriculture and Agri-Food Canada issued a 2nd version of the Canadian Food Traceability Standard (Can-Trace 2006a, 2006b). The standard supports a one-up-one-down model for traceability and therefore stipulates that data must be "collected, kept and shared" by all the participants in the food supply chain to accomplish this (Can-Trace 2009a).

Can-Trace is a collaborative, open, industry-led initiative to define and develop minimum requirements for national whole-chain tracking and tracing standards based on the GS1 system (Can-Trace 2009b). Can-Trace completed and validated the 1st version of the Canadian Food Traceability Data Standard in 2004. GS1 Canada is the initiatives' secretariat. Can-Trace has produced a number of reports including reports of pilot projects on produce, pork, beef, and multiple ingredient products, and has produced technology and integration guidelines (Can-Trace 2009c).

Canada, like the EU, Japan, and the United States, employs a farm-to-table approach to ensure quality throughout the food supply. However, an important difference is that Canada takes this process 1 step further by including the plants and animals on which the food depends under this policy. This means that seeds and fertilizers are inspected and regulated along with the feed and food product itself. At the other end of the spectrum, Canada participates in many similar programs to the United States that aim to educate the public on safe food preparation and risks associated with certain practices.

IBM and the Province of Manitoba tested a new system of digital tracing in a project that moves the province toward implementing a provincial traceability program. The project involved 16 supply chain partners including beef and pork producers, animal feed ingredient producers, feed manufacturers, farmers, processing plants, truckers, and a retail grocery chain. In the project, data about product movement, animal history and characteristics, processing history, and transportation were tracked throughout the complete value chain. The project incorporated GTNet software from IBM business partner TraceTracker. The project demonstrated that it is possible to securely and accurately gather and analyze data about a piece of meat from a variety of sources and share that information, at any step in the process (TraceTracker 2008).

5.4 Current United States regulations related to traceability

5.4.1 Bioterrorism Act of 2002. The Bioterrorism Act of 2002 (BT Act), and the recordkeeping requirements contained in the Act, represented a major step forward in the implementation of a product tracing system for FDA regulated food products. This Act created a paper trail documenting food distribution, so as to determine the source of contamination in the event of a foodborne illness outbreak.

People who "manufacture, process, pack, transport, distribute, receive, hold, or import food" in the United States, as well as foreign food transporters in the United States, are required to maintain records to identify the previous sources and subsequent recipients of the food. Exclusions include: farms, restaurants, food processed for personal consumption, and outer food packaging. Direct to consumer distributors are not required to keep records of the people to whom they sell. Food transfers *within* a company are not subject to recordkeeping. Also excluded are food samples used for quality assurance, research or analysis purposes that are not consumed.

Establishments exempt from recordkeeping requirements but subject to record access requirements include food retailers with 10 or fewer employees, inner food packagers, nonprocessing fishing vessels and nonprofit food establishments.

Required records for food received and released must include: previous/subsequent source (including full contact details), description of food (brand name and variety), date received/released, lot or code number (if relevant), quantity and packaging. When food is released, records additionally must include information "reasonably available" identifying specific sources of each ingredient to each lot of finished product. In cases where food processors commingle ingredients such as flour from different suppliers, FDA accepts that manufacturers may not be able to identify 1 specific source.

Records must be retained for 6 mo to 2 y depending on food type. Records must be provided to FDA not more than 24 h after requested. The format of the record is not specified. Compliance took effect between 2005 and 2006 depending on business size.

5.4.2 Reportable food registry. Effective September 8, 2009, "responsible parties" (that is, facilities that are registered with FDA as part of the BT Act of 2002), are required to submit an electronic report if they have reason to believe that an FDA-regulated food "may cause serious adverse consequences or death of humans or animals." There are 2 aspects of this regulation that relate to product tracing. The first is the fact that this report must be submitted through an electronic portal; paper-based reports are not accepted. The 2nd element related to traceability is the information that a company needs to provide. The facility identifier to be used is the facility registration number. The quantity of food and information on the packaging, such as a universal product code (UPC), brand names, and so on must also be submitted. The portal provides fields to enter lot-specific information, if available. Notification to the immediate supplier and immediate recipient(s)—the same parties covered under the BT Act recordkeeping requirements—may also be required, as well as providing contact information for them. When a report is registered, it is assigned a unique number which should be provided to those contacts, who would, in turn, reference it in their registrations. This "cascade" should theoretically show a supply chain for the product. The information submitted is not shared with the public or others; however, it is subject to Freedom of Information Act with the standard redactions.

5.4.3 Perishable Agricultural Commodities Act. The Perishable Agricultural Commodities Act (PACA) of 1930 facilitates fair trading practices in the marketing of fresh and frozen fruits and vegetables in interstate and foreign commerce. Many in the produce industry cite the PACA requirements as providing recordkeeping that facilitates traceability.

Overseen by the USDA, PACA regulates the buying and selling of produce to prevent unfair trading practices and to help ensure that dealers get what they pay for and get paid for what they sell, including when their customers go out of business, declare bankruptcy, or simply refuse to pay for the fruits and vegetables received. It aims to prevent the destruction or dumping of farm produce without good and sufficient cause and requires commission merchants to account for all produce received. Sellers and buyers must pay a license fee to do business, and these fees fund a trust program that resolves disputes and protects sellers from nonpayment when buyers become bankrupt.

In general, any person who buys or sells more than 2000 pounds of fresh or frozen fruits and vegetables in any given day is required to be licensed under the PACA. Wholesalers, processors, truckers, grocery wholesalers, and food service firms fit into this category.

Commission merchants, brokers, and growers' agents, who negotiate the sale of fresh produce on others' behalf, are required to be licensed. A broker handling only frozen fruits and vegetables, however, does not need a license until sales invoices exceed $230000 in a calendar year. A person selling at retail is subject to a PACA license once the invoice costs of fresh and frozen fruits and vegetable purchases exceed $230000 in a calendar year.

5.4.4 Country of origin labeling. The 2002 and 2008 Farm Bills amended the Agricultural Marketing Act of 1946 to require retailers to notify their customers of the country of origin of certain meats, fish and shellfish, fruits and vegetables, nuts, and ginseng, through signs and labels.

The statute went into effect on September 30, 2008, and the final rule took effect on March 16, 2009. Exemptions include meat products sold in restaurants, as well as processed products that have been cooked, smoked, or restructured such as hot dogs, lunch meats, cooked products, breaded products, products with meat as an ingredient (for example, spaghetti sauce with meat), and so on.

Any person engaged in the business of supplying a covered commodity to a retailer, directly or indirectly, must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of the product. Such records must identify the product unique to that transaction by means of a lot number or other unique identifier, for a period of 1 y from the date of the transaction.

Establishments that slaughter livestock are considered initiating suppliers of a covered commodity. The Agricultural Marketing Service, the agency administering the law and regulations, has indicated that the initiating supplier (packer) must have records in its possession that substantiate the country of origin of the meat product at issue.These records can be in a variety of forms, and can include animal health records, import or customs documents, as well as producer affidavits. Suppliers must make records available for review within 5 d of a request for such records.

At retail, records and other documentary evidence relied upon at the point of sale to establish a product's country(ies) of origin also must be made available to USDA representatives for so long as the product is on hand and that information must be provided within 5 d of the request being made. For prelabeled products, the label itself is sufficient evidence on which the retailer may rely to establish a product's origin.

5.4.5 Organic Food Protection Act. The Organic Food Production Act of 1990 required the USDA to develop national standards for organic products. These regulations are enforced by the USDA through the Natl. Organic Program (NOP). Fully implemented in 2002, the NOP is the federal regulatory framework governing organic food in the United States. The NOP covers fresh and processed agricultural food products, including crops and livestock. The NOP develops, implements, and administers national production, handling, and labeling standards for organic agricultural products. The NOP also accredits the certifying agents (foreign and domestic) who inspect organic production and handling operations to certify that they meet USDA standards.

Growers and processors of organic produce that we spoke to often noted that the organic produce industry had been practicing traceability longer than most other parts of the produce industry due to the recordkeeping requirements for organic operations.However, although organic growers must trace inputs, they do not necessarily have to trace outputs.Tracing inputs is the documentation of a practice within a production cycle, not in the marketing of fruit.Also, some organic growers are not subject to the BT Act, in that they are farms, not processors or shippers or food.

Under the NOP, farmers and food processors who wish to use the word "organic" in reference to their businesses and products must be certified organic. Producers with annual sales not exceeding $5000 are exempted and do not require certification (however, they must still follow NOP standards, including keeping records and submitting to a production audit if requested, and cannot use the term "certified organic"). A USDA Organic seal identifies products with at least 95% organic ingredients.

An organic system plan commits the producer or handler to a sequence of practices and procedures resulting in compliance with regulations. Accreditation qualifies the certifying agent to attest to whether an organic system plan comports with the organic standard. An organic system plan contains 6 components, which are below:

1. Practices and procedures
2. Substances used
3. Monitoring techniques used to verify that the organic plan is being implemented in a correct manner
4. Recordkeeping to preserve the identity of organic products from certification through delivery to the customer
5. Management practices and physical barriers established to prevent commingling of organic and nonorganic products
6. Site specific information

6.0 Current Media to Aid in Product Tracing

There are several technologies that are used to transfer information. These technologies apply different media and infrastructure, the simplest of which is pen and paper. Bar codes are also used to accommodate different amounts of information and radio frequency identification (RFID) is currently the most technologically complex medium (Table 1). Other potential media include vision/imaging systems, dot peening, and laser etching. A discussion of the various media is provided in the section below.

6.1 Alphanumeric notes

Information could be presented and recorded simply using handwritten or printed notes. This has the advantage of low cost, but obvious disadvantages of potential illegibility, transposition, language barriers, fading and other physical damage, and so on. Information supplied or recorded in this fashion may or may not be entered into a computer database. If this type of data entry is done as an additional step, there may be additional opportunity for errors in transposition.

6.2 Bar codes

A bar code symbol consists of parallel, adjacent bars and spaces with predetermined width patterns that are used to represent data. Bar codes are an automatic identification technology, which facilitate accurate and fast collection and communication of data. There are several types of bar codes such as the traditional U.P.C. codes that are familiar to consumers and businesses, and other types that are gaining acceptance and use, for example, the 2-dimensional (2D) bar codes on electronic airline boarding passes and printed grocery savings coupons.

The use of bar codes requires 2 main pieces of equipment: (1) a printer for printing of the bar codes; this can either be done by the packing/sending company on site or with pre-printed labels, cartons, and containers, and (2) a reader or scanner used by the receiving company to scan the bar code to collect information contained therein. The scanner is moved across the bar code symbol, from side to side, to analyze the pattern of bars and spaces and collect the data content. It is typically light or laser-based, although there are some that are image or camera-based; they capture the image and transmit to a database for information. Many bar codes also provide alphanumerical information below the bar code so that information is also human readable and can be manually captured. Besides the hardware, software is needed to print the symbols in a standard format and to collect, process, and communicate the data.

An advantage to using bar codes is that, depending on the bar code format selected, a substantial amount of information can be contained in it and bar codes are relatively inexpensive. However, adhesion of bar codes or other types of labels to some products (such as cantaloupe) may be problematic. The fruit does not have

Table 1—Details, benefits, and limitations of bar codes and other media.

Technology system	In use?	Description	Benefits	Limits
GS1 System	Yes	GS1 System enables unique identification of products; data can be encoded into data carriers such as bar codes. A data carrier is a means of representing data in machine readable form. The GS1 System uses the following data carriers.	Wide acceptance across a number of industries; can be integrated into production, shipping, and receiving systems; data can be communicated in electronic data interchange messages between trading partners	Bar codes require line of sight scanning
		• The EAN/UPC symbology family of bar codes (UPC-A (12 digits), UPC-E, EAN-13 (13 digits), and EAN-8. GS1 Databar, Data Matrix. • ITF-14 carry 14-digit identification numbers not expected to be used through the point-of-sale • GS1-128 Bar code symbol is extremely flexible and can encode various data elements • GS1 DataBar is a linear symbology used for small items	Inexpensive; globally accepted	
2D Bar codes	Yes	Two major groups. Data matrix symbologies look like a matrix of geometric shapes. Multi-row bar codes look like linear bar codes but the bar codes have been shortened and stacked on top of each other horizontally.	Smaller than normal bar codes and hold more information	Must be read in a certain position and can be read only by certain equipment; costs slightly more than normal bar code
Composite Bar codes	Yes	Composite symbols combine a linear and 2D symbol. Symbols are printed close together and hold linked information.	More information can be stored	Must be read in a certain position and can be read only by certain equipment
Radio Frequency Identification RFID	Yes	A tag is attached to the product. The tag consists of a chip that stores information and an antenna that allows the chip to be read by radio waves from a reader device. The radio waves detect the chip signal and transfer the information to a computer. Two types of tags exist. Passive tags are powered by an external source and have shorter reading ranges but longer operational lives. Active tags are powered by an internal source and have longer reading ranges with a shorter and more expensive operational life.	Line of sight to the tag is not required and multiple tags can be read virtually simultaneously, may reduce labor costs, no manual screening, variable memory; tag memory can be rewritten or appended	May be too expensive for low cost commodities, tags may interfere with recycling and biodegradation processes, tag durability and life is unknown, large quantities of tags must be stored by the user since they cannot be manufactured at the point of use, radio interference
Electronically Readable Coding Techniques	Yes	Electronically readable codes are attached to a product through normal printing procedures but with special inks.	Not as sensitive to dirt or bad conditions, can be invisible, cheaper than RFID	Flexibility and reading range not comparable to RFID
Edible Bar codes	No	Applied directly to food, and considered a food additive. Information can be encoded on a microscopic particle. Binary codes are usually used because they are easier to read.	Reach through real time documentation	Expensive, still in research, government regulations on food additives, need advanced technology for use and reading

Table 2—Comparison of types of RFID tags.

Tag type	Active tags	Passive tags	Semipassive tags
Definition	Internal battery powered	Tags powered solely by radio frequency	Internal battery can power sensors OR increase range
	Operate at 455 MHz, 2.45 GHz, or 5.8 GHz	No battery, transmitter	
	Either transponders or beacons		
Advantages	Range: tens—even hundreds of meters	Low cost (20 to 40 cents)	Relatively low cost compared to active tags
		No maintenance	
		Can operate at low frequency, high frequency, and ultra-high frequency	
Disadvantages	More expensive, $10 to 50	Range—several meters	Range—several meters
	Limited battery life		Limited battery life

a smooth, uniform surface for adhesion hence labels may come off. Also line-of-sight access to the bar code is necessary in order for it to be scanned (as opposed to RFID, which does not need to be visible for scanning).

6.3 Radio frequency identification devices (RFID)

RFID-based systems are arguably the most technologically complex systems available today. It is a system that uses radio waves to track items. RFID technology consists of tags (active or passive, summarized in Table 2) and readers.

Active RFID tags require a power source and can broadcast information independent of a reader. Active RFID devices have a battery and tend to have a longer range than passive devices and they can be programmed to periodically "broadcast" their information to readers within their signal range. These tags are generally larger in size, about the size of a brick, to accommodate both the battery and a larger antenna required for additional broadcast range. Additional data can be stored on the tag for future download onto a computer or reader (Labuza 2008) and some may also interface with a variety of sensors (temperature, light, vibration, and so on) that can record conditions during shipment or while in storage. Active tags are more expensive than passive tags.

A passive RFID tag has no power source (battery); it is simply a chip with an antenna. It is programmed using a reader, and transmits information only when a reader powers the tag and a portion of that radio energy is reflected back to the reader. It can be "written" either at the point of manufacturing or during the packaging or shipping process. When run through a gateway (scanner/reader, including handheld), it puts out a signal of a specific wavelength. The chip is powered by the signal from the reader and sends back an interference pattern which the gateway recognizes. That information is the code (like that in a bar code). UPS and Amazon use this technology to ship and track packages. Passive RFID technology tells you when the product passes through various portals, so there need to be enough stops along the way to create a path. The tags contain limited amounts of memory and many only contain a simple identifier that is then used to reference more detailed information in a data store elsewhere. Advances in passive RFID technology have occurred in the past few years and some passive RFID tags are now available with additional on-board memory that can contain additional information that may be gathered as the product progresses through the supply chain.

A 3rd type of RFID tag, a semipassive tag, is powered by a flat battery, allowing the shape to be flat and dimensions to be much smaller. These chips can resemble credit cards in shape. They are powered through receiving signals from a specific frequency emitted from a RFID reader. Once the chips recognize the frequency, generally either high-frequency or ultra-high-frequency waves, they activate and take action as they are programmed. High-frequency energy is used in powering the chips through their magnet element but the reader requires a closer range to the chip to function, usually within centimeters, and is therefore more useful in lower volume applications such as store loyalty cards (Mccombie and Welt 2009). Ultra-high-frequency energy can power chips, through backscatter radiation, from a farther distance, usually between 2 and 10 ft, and are more useful with product inventory (Mccombie and Welt 2009). These chips are generally larger in size, around the size of a brick, because this data transfer technique requires large antennae to return the energy from the reader. Another unique characteristic of these tags is that initial data are not stored internally. For example, some companies market an RFID tag which continually senses temperature but instead of storing these data, it uses this information to calculate shelf life and stores the resulting data. Less information is stored on semipassive than active tags (Labuza 2008). One limitation of this RFID tag is the low battery life.

RFID tags come in a range of shapes and sizes. The following are the most common:

- Label: The tag is a flat, thin, flexible form
- Ticket: A flat, thin, flexible tag on paper
- Card: A flat, thin tag embedded in tough plastic for long life
- Glass bead: A small tag in a cylindrical glass bead, used for applications such as animal tagging (for example, under the skin) Integrated: The tag is integrated into the object it is tagging rather than applied as a separate label, such as molded into the object
- Wristband: A tag inserted into a plastic wrist strap
- Button: A small tag encapsulated in a rigid housing (RFID Journal 2009)

6.3.1 RFID applications. RFID technology is being explored for applications in supply chain management. It currently complements the bar code system. Stores such as Wal-Mart and Sam's Club have already implemented a system based on RFID on cases and pallets (Weier 2008). Wal-Mart Club is one of the largest backers of the technology and has put it to use to in an effort to improve supply chain efficiency, reduce labor costs, and reduce shelf out-of-stocks, apparently resulting in increased sales. Electronics retailer Best Buy Co. Inc. also experimented with item level RFID on DVDs and video games. The initial trial was linked to increased DVD sales due to reductions in out-of-stock merchandise (Welt 2009). Retailer Bloomingdale has piloted RFID tags on selected apparel items for inventory management (Arens 2009).

Other applications of RFID use include Electronic Article Surveillance (EAS) to prevent shoplifting and secure libraries, automatic tollbooth passes, SpeedPass for cashless payments such as that used by Mobil/Exxon fueling stations, Visa's payWave, MasterCard's PayPass, and American Express's ExpressPay (AIM Global 2009; Texas Instruments 2009). The safety of these devices has been debated but little threat is discovered (AIM Global 2005; Rieback 2006).

RFID is also used in animal tracking. Pets and livestock can be implanted with a subdermal RFID chip, improving herd management and allowing lost animals to be identified (Welt 2009). Under-the-skin chip systems are now widely used for pets. The VeriChip or VeriPay is a type of RFID chip that is designed to be implanted under the skin. While it may only contain a 16-digit serial number, this information is linked to a database and can also be picked up by any compatible reader.

6.3.2 Advantages of RFID. The primary advantage of RFID is that it does not necessarily require a direct line-of-sight between a reader and the tag to read the tag. This is because it uses radio signals, which can read a multitude of tags almost simultaneously. Bar code read rates depend upon the rates at which they can be presented to readers. RFID tags can be read at a rate of tens or hundreds of tags per second. However, this inherent advantage of RFID is mitigated by the rates at which items such as containers, pallets, cases, and items can be physically moved through the supply chain. Since bar code readers are capable of reading data on items at the highest speeds attainable within the supply chain, this RFID advantage may not be fully exploitable (Welt 2009). The low need for human intervention, however, makes it possible to "read" items moving in the supply chain at many additional points in the supply chain without adding costly labor to the process. Another potential advantage of RFID is that data can continue to be loaded at various points along the supply chain (assuming that each handler has the technology needed to add data), although current standards are designed specifically to avoid continually loading tags with information. Some RFID tags can be reused several times.

RFID has also helped introduce standards and serialization to the industry at a relatively low cost per tag. With bar codes, each package of an item contains an identical product code for the manufacturer and the product type. The identifiers used with RFID expand upon today's product codes by adding a unique serial number to each "instance" of a particular type of product. That serialized information can be entered into a database to determine the source, expiration date, and other useful information about a particular item and to provide end-to-end traceability about specific items over time.

6.3.3 Disadvantages of RFID. The major disadvantages of RFID include cost, complexity, and environmental sustainability. The cost of tags and infrastructure needed to load and capture data is significantly more than the other systems. For example, an analysis estimated that the cost for members of the Leafy Greens Marketing Agreement to use active RFID tags was roughly $1.3 billion, while the use of passive tags was estimated at almost $110 million. These costs are higher than the estimated use of bar codes, which was approximately $3 million (Institute of Food Technologists 2009). RFID signals are radio waves and can be difficult to read in the presence of high concentrations of moisture. High-moisture or liquid products are good absorbers of electromagnetic energy used for RFID, which interferes with low power RFID transmissions. Designs have improved to keep the unit moisture-free in a food environment. In addition, many products contain metals or metal packaging which can shield, scatter, and reflect radio signals, resulting in unpredictable RFID performance. While RFID chips themselves are fairly rugged, the connection between the chip and antenna can become damaged affecting the proper functioning of the tag. Also, damages can occur in the readers that prevent product information from being recorded. If damages are not caught then knowledge of inventory can be affected. RFID tags typically contain relatively expensive materials that are not recovered and also may interfere with traditional material and energy recovery processes.

There have been some reports of RFID technology being hacked and allowing access to the information stored. Smart tags and identification cards with RFID concern some with the possibility of security issues. Advocacy organizations, such as Consumers Against Supermarket Privacy Invasion and Numbering (CASPIAN) and FoeBud, a German group of RFID and privacy activists, strongly oppose item level tracking, since these technologies may allow for undisclosed wireless customer tracking. Also, threats of the ability to send viruses out over RFID readers and to further infect all scanned RFID tags causes concern in industries considering implementing this technology (Rieback and others 2006). Additionally, some consumers have devised methods to detect and "kill" RFID tags to disable the devices without authorization. One such example is the RFID Zapper, created using an off-the-shelf single-use camera and a coil of wire. The device uses the capacitor in the camera (normally used to power the flash) to pass a high voltage through the coil, overpowering the RFID tag and causing the circuit to overload. RFID tags can also be disabled by placing them in a microwave oven; however, this can be dangerous and can cause damage to the tagged item and the microwave oven as well.

Organizations like GS1 and its EPCglobal subsidiary are working with its members to enhance RFID technology to address consumer privacy concerns and to promote the responsible use of the technology.

6.4 Other media

6.4.1 Vision or imaging systems. Imaging systems involve the use of a camera coupled with other identification symbologies such as 2D data matrix bar codes to capture information. The key with machine vision is it can hold the same information in the images as would RFID tags. They offer an effective and less expensive alternative to RFID and are becoming more common. Also, there is no need to maintain an inventory of the tags as is the case with RFID. For vision systems, codes can be printed as needed at the point of use. Vision systems using digital camera-type sensors are commercially available. The focus has been in vision sensing (cameras) for automated systems without consideration of their traceability capability. A spin-off of the vision technology is the use of a camera equipped cell phone as an image/code reader. Software in the cell phone can interpret the image and then use high-speed cell connections (3G+) to access any information available through the internet.This technology already exists and can be used for tracking and tracebacks. Research is being done on applications that will deliver content specific information to the user (for example, nutritional information to a customer, track and trace data to an inspector, shipping information to an employee in shipping and receiving, and so on). The major advantage is many people who need information will not need additional hardware beyond their regular cell phone. Some suppliers propose that this type of technology will facilitate the capture of information in growing fields where the accessibility of other electronic information is limited.

6.4.2 Laser etching and dot peening. Laser etching directly on items such as produce has been proposed as an alternative to labeling with a sticker. A burst of light is used to imprint information on the surface of a product. Dot peening (also termed micro-percussion marking) involves the use of a vibrating tool that makes indents in a material (for example, a plastic water bottle) without weakening the material. The advantage to these techniques is that they cannot be washed away or altered the way ink can. Although proponents of these technologies cite cost efficiency, some in the produce industry noted that the damage to the skin, although only a few microns deep, would result in increased spoilage rates. In testing for fruit decay, the fruit was inoculated with decay organisms and then etched with a laser. No pathogens were found in the peel or the fruit interior. The scientists found that the laser cauterizes the peel, much like when a laser is used on human skin. The cauterized area is impenetrable to pathogens and decay organisms and resists water loss (USDA 2009).

6.5 Summary

The *type* of media used to transmit information is completely independent from the quality and type of information transmitted. Standardization of such information is often lacking thus using a complex medium such as RFID does not bring one closer to effective traceability. There is a need to standardize the information conveyed along the supply chain, regardless of the technology selected.

7.0 Tracing in Nonfood Industries

Many industries have employed product tracing to address specific issues faced within that industry. IFT examined several nonfood industries to determine if their approaches would be useful in informing systems that might be considered for food product tracing. The results are summarized in Table 3.

7.1 Automotive industry

Traceability is viewed as a means to mitigate cost and danger associated with the recall procedure in the automotive industry.

Solutions software is used to avert improper assembly location, utilization of defective equipment, and to establish a monitoring system for vehicle components. An essential component of automotive traceability is the need for tracking individual auto parts. A distinction is made between part tracking and part traceability. Part tracking utilizes bar code technology to locate the part at any point in time. The intention of this tool is to improve company efficiency. Part traceability, however, serves a measure used to track the history of a part, including any machinery used during the construction process. This is in response to government regulation, as well as having a warranty-based purpose.

In 2000, legislation known as the TREAD (Transportation Recall Enhancement Accountability and Documentation) Act was passed by Congress. This Act requires automobile companies to notify the federal government of consumer complaints in an attempt to spot defects earlier. In return, the B-11 Parts Identification and Tracking Standard was established by the Automotive Industry Action Group. This framework provides automotive original equipment manufacturers and suppliers with a standardized set of guidelines for placing passive RFID tags on tires/wheels. The postimplementation period of TREAD has resulted in a myriad of cost/benefit analyses by auto industry experts (Warranty Week 2003).

As with many deviations from the *status quo*, implementation was met with heavy opposition due to enormous cost projections. Obstacles to traceability implementation included storing and accessing information for thousands of vehicle components a day and differentiating between serial numbers and lot numbers.

RFID and DPM (direct part making) are common technologies used for automotive part tracing. Direct part making is the act of applying permanent 1-dimensional or 2-dimensional codes and/or human-readable information directly to an individual part using laser, chemical, ink, or physical imprint. The value of this method is its permanent identification number which sustains harsh environmental conditions and combats supply chain mismanagement. RFID benefit lies in its ability to store part history (genealogy), as well as real-time information.

7.2 Pharmaceutical

This industry attempts to trace pharmaceuticals from manufacturers to patients. Traceability is of increased importance in this industry due to the continual rise of counterfeit drugs. Counterfeit drugs seem to flourish due to internet purchasing, demands for lower costs, and the prevalence of unlicensed markets. Additionally, improper supply chain management costs the pharmaceutical industry an estimated $30 million per year. Supply chain management to control costs and assure product authenticity is therefore the focal point of pharmaceutical industry traceability.

As a bare minimum, pharmaceuticals are legislatively required to have a Natl. Pharma Code (e.g., GTIN), Lot Number, Expiry Date, and Serial Number. Current electronic labeling includes Pharma Code, supplier/importer info, size, pharma product group, and special controls, if applicable.

Bar code technology is still frequently utilized although RFID technology can potentially be used as a tracing tool for pharmaceuticals. RFID technology has initially been used for pharmaceuticals with a high incidence of counterfeit production. RFID tags serve as a means of unique product identification. Tags are placed on folding boxes, bottles, or pallets. Many companies are currently conducting pilot programs to acclimate their companies to the implementation of these new technologies.

In 2003, GS1 constructed the European Healthcare Initiative in support of utilization of the GS1 System of Standards in the European healthcare supply chain. The BRIDGE Project (Building Radio Frequency Identification in the Global Environment) is being conducted to implement systematic traceability in the European healthcare sector. Thirteen million Euros have been allotted to this program. One of the ultimate goals of this pilot program is to be able to trace pharmaceuticals from patient

Table 3—Comparison of tracing systems and objectives in nonfood industries.

Industry	Objective	Impetus	Means
Auto	Trace parts during assembly	Efficiency	Bar code
	Trace potentially defective parts	Regulation	Passive RFID
Pharmaceutical	Prevent counterfeiting	Legislation is proposed	Bar code/RFID
Toy	Product safety	Supply chain management (regulations address recall, not traceability)	Put manufacturer location/date on product
Post/parcel	Correctly route mail	Economics	Bar code/RFID
Clothing	Reduce counterfeiting, address allergen concerns, assure organic, and so on	Customer relations	Evolving; early stages of development
Appliance	Document product testing	Decrease warranty costs	ID tags
Animal	Trade from birth to slaughter for disease control	Regulation	Ear tag/RFID

consumption to the initial point of product manufacturing, including all intermediaries.

7.3 Toy industry

As an industry which must take extreme precautions, the toy industry focuses primarily on supply chain management. Like the pharmaceutical industry, supply chain management is of particular concern to the toy industry due to the fact that minor errors can be potentially fatal. In the toy industry company size determines influence; larger original equipment manufacturers (OEM) possess more supply chain and product safety control.

The toy industry approach to traceability includes providing manufacturing location and date. Product testing seems to be of significantly more concern than traceability in the toy industry. Traceability practices are audited as a component of the company's larger factory audit. Addressing traceability practice, the Toy Industry Assn. stated, "Wherever possible the factory identification and date code will be on the product as well as the retail packaging (either the largest component, on a sewn-in label (soft toys), within a battery compartment or similar location)." If it is not feasible to place identification information on the product it should be placed on retail packaging. A mode of identification is mandatory on any master carton used for shipping from the factory to retailer/brand warehouse.

To provide another measure in favor of consumer safety, in 2008, the government passed the Consumer Product Safety Improvement Act. The ultimate goal of this Act is to strengthen the Consumer Product Safety Commission and to protect children from faulty products. The Act requires manufacturers of various children's products to supply consumers with a consumer registration form, and to maintain consumer information and any other vital consumer data. While this does not provide information for all points in the product pathway from manufacture to consumer, it does allow the manufacturer to contact those who may have purchased defective products, and puts the onus of the recall procedure on the manufacturer.

Potential criminal punishment and financial loss make this legislation harsher than previous ones. Stericycle, a recall management service, is helping manufacturers, retailers, and distributors during this transition period. They provide numerous recall-focused services, the most pertinent being a "field force." The assemblage of a "field force" to investigate the selling of recalled products forces manufacturers to maintain accountability. They are now liable for the selling of defective goods.

7.4 Parcel

Parcel traceability aims to follow a mailing from its origin to its deliver. Parcel/postal traceability is largely facilitated through technological solution companies. Its implementation is achieved through bar code technology or RFID technology. Each parcel is assigned a unique bar code number or RFID tag which serves as a mode of identification. The main objective of postal tracing is to avoid misrouting parcels and improve processing of information.

Parcels are scanned during handling/procedures. This provides the company with internal traceability. These are closed systems, since the package is picked up and delivered by the same firm.

7.5 Clothing

Clothing traceability is conducted largely for the reassurance of the consumer. Manufacturers provide consumers with traceability information to establish an ethical rapport. Consumption of organic clothing is currently increasing due to rising consumer awareness. Clothing traceability is of concern to consumers because of the presence of potential allergens, to avoid patronizing companies who utilize child labor, and to inform those who are environmentally conscious. Recently one company which produces garments from merino fiber (wool) has introduced a clothing traceability resource which can trace clothing back to the facility used for production. This resource documents everything from animal living conditions to farmer information.

Transparency is also another reason for clothing traceability. Consumers feel confident in purchasing a product that they can follow throughout the supply chain. It represents corporate integrity, which a lot of consumers feel is uncharacteristic of large companies. This practice falls under the umbrella of corporate social responsibility.

Traceability in the clothing industry is relatively new. Proposed improvements to the current system are organic certification for natural fibers, use of technology, and improved industry standards, auditing, and verification.

7.6 Appliance

Product testing is of immense significance to this industry. Consumers purchase these products with the intention of long-term utilization. Traceability has been identified as one of the core measures where implementation can prevent defectiveness. In this industry product, process, assembly, and inspection data are entered onto ID tags.

Traceability's utility in this industry also serves as a method to document proper testing has been conducted. In the appliance manufacturing industry, for example, there are examples of warranty costs being reduced by 90% with introduction of an integrated fully traceable safety testing system (Manufacturingtalk 2006). This proves that there is a consumer safety benefit as well as a cost reduction that encourages traceability.

7.7 Animal identification

The USDA Animal and Plant Health Inspection Service (APHIS) introduced the Natl. Animal Identification System (NAIS) to track all species of U.S. livestock and poultry from birth to slaughter to protect the health and economic well-being of those industries. The purpose is to serve as an effective way to prevent spread of disease, identify origin of outbreak, assure food safety, retain foreign market accessibility, proceed with recall procedure, and for businesses to minimize legal and cost expenses. Animals are not traced after slaughter since this program is mainly for disease prevention.

The current system involves 3 components:

1. Facility registration;
2. Animal identification (animals that move in groups do not require individual ID); and,
3. Database construction (privatized).

NAIS is a voluntary program that currently has 510000 registered premises, which is 36% of total livestock premises in the United States. USDA would like to have a higher level of participation. Each location is given a unique PIN, which is a 7-digit code with numbers and characters. The last character is a check digit. The cost burden is taken on by industry and government, and profit margins at the farm or ranch level are an issue for participation.

Most registered animals have a visible tag with a unique identifier on it, called an animal identification number (AIN) or group/lot identification number (GIN). Most dairy cattle are identified. USDA supports any form of identification farmers wish to use, including new technologies such as RFID. USDA staff believes automated data capture may become the future of traceability.

Animal tracking information is sent to state or private animal tracking databases (ATDs) to which USDA must submit a request to view for animal disease information. Wisconsin and North Dakota house the only state level ATDs currently, and there are

17 private ATDs. It is up to the customer and ATD provider to determine how information is shared and used. This has been a great way to enhance federal-state partnerships for USDA. The majority of the ATDs provide other services for users. Many farmers use the ATDs for management purposes and animal information is therefore continually updated by farmers. Movement of animals is entered in a 24-h time period, which USDA considers to be very timely. USDA has had some issue with incorrect information being entered into the system and are looking into ways to improve accuracy.

The USDA is continuing to look at solutions that work in commerce and to examine the long-term direction of the NAIS.

As shown in Table 3, the motivators for traceability in different industries are different. Since they are addressing different problems, it is not surprising that they use different solutions. In general, no other industry seemed to be an exact parallel to the food industry. Although the food industry could learn from the experiences of other industries, a turn-key solution to traceability in food cannot be found from models used in other industries.

7.8 Agricultural inputs

AgGateway is a nonprofit organization of 87 companies in the agricultural industries, divided into 5 "councils": seed, crop protection, crop nutrition, fertilizer, and allied providers (traceability solution providers). Member revenue ranges from a million to a billion dollars. Their goal is to improve the agricultural businesses by supporting e-business and improving the connectivity (transfer of information) between trading partners.

They began as several organizations, each working on different standards for their industries, and joined together in 2005 to improve e-business for agriculture. The Accelerated Electronic Connectivity project was the 1st instance where they utilized their standards. They provide several services for members, one of which is providing GLNs. GLNs provide a global supply chain solution for the identification of physical locations and legal entities. They currently have 3.5 million entities identified with GLNs. GPS coordinates are associated with the GLNs. AgGateway purchases these from GS1, assigns them, and maintains them for members, although it is up to a company to determine what needs a GLN. Rules, security, and duplication checks for GLNs are built in. The group maintains a centralized database called the Ag. Industry Identifier System (AGIS). Of main interest is that AgGateway establishes guidelines and develops standards, and all members agree to adhere to the standards. Participation is voluntary.

The standards are open source and free of charge. They can be used by nonmembers. The Nexus E to E system integrates their standards and is open source. The advantage of membership is that members participate in setting the standards via councils.

They have adopted an international specification (ebXML) that defines how trading partners can pass extensible markup language (XML)-based information back and forth either from web-server to web-server (synchronously, or real-time) using HTTPS (SSL) or via e-mail (asynchronously, or at different times). This specification is not specific to their industry, but is designed as a universal standard that many industries can use to send information between trading partners. The specification defines the structure of the messages, the security around sending them, how they will handle errors, and so on. What the specification leaves intentionally unspecified is what the "payload" looks like. The idea is that each industry can adopt their own payload, but still use an ebXML-compliant infrastructure to send and receive messages.

The advantage is that a packaged foods company could build one ebXML.compliant messaging system to use with many of their trading partners, from different industries. For example, they could receive product movement XML payloads from their ingredient suppliers and use the same infrastructure to send messages with invoice XML payloads to a wholesaler who purchased their product.

8.0 Current Practices in the Food Industry

Product tracing is needed to respond to a "triggering event." In the United States, traceability in the food industry is often related to food safety, even though product tracing is reactive, and cannot prevent contamination. However, there are other kinds of "triggering events," even in food. In Europe, the tracking of food derived from GMOs may be a concern. Whatever the motivation, traceability requires documentation and recordkeeping.

8.1 Assessment of current industry practices

IFT spoke with many food industry trade associations and other stakeholders to establish the current state of traceability and to get a sense of upcoming industry initiatives. A summary of the initiatives currently underway is presented in Table 4. There are a number of initiatives in various stages of development, with the Produce Traceability Initiative (PTI) seemingly the most advanced. The Canadian Produce Marketing Assn., Produce Marketing Assn., and United Fresh Produce Assn. launched the PTI to help the industry maximize the effectiveness of current traceback procedures, while developing a standardized industry approach to enhance the speed and efficiency of traceability systems for the future (Produce Traceability Initiative 2009). The PTI vision outlines action to achieve supply chain-wide adoption of electronic traceability of every case of produce by 2012. A PTI Action Plan Implementation Toolkit has 7 milestones and provides step-by-step best practices, definitions, and explanations to help understand the milestones. The 7 milestones are: (1) obtain a GS1 company prefix, (2) assign GTIN numbers, (3) provide GTIN information to buyers, (4) show human readable information on case, (5) encode information in a bar code on case, (6) read and store information on inbound cases, and (7) read and store information on outbound cases.

An interesting state initiative to note is that the U.S. Farm Bureau funded the Hawaiian Dept. of Agriculture to conduct a pilot study, involving tomatoes using RFID applied at the case level at the pack house. Initially, 6 growers participated, with cases being scanned as they are shipped to a produce wholesaler. The system is hosted on the state server since the source of funding was federal. Data are provided in real time or as a batch load (collected at a local computer at the farm level and uploaded to the State of Hawaii). The wholesaler participating in the pilot has RFID enabled dock doors at the distribution center (DC). They assume that whatever is shipped is received (recognizing that some cases in the middle might not be read). The wholesaler in the pilot does not ship full pallets of tomatoes to individual store locations. They scan individual cases with an RFID handheld scanner. That is when they are able to reconcile the amount received. Two retail stores are outfitted to scan RFID and also have an RFID reader at the trash compactor to read empty cases.

IFT also spoke to scores of representatives from all segments of the FDA-regulated food industry, including several site visits to farms, dairy processing plants, fresh-cut produce operations, terminal markets, retail DCs, retailers, and others. IFT held 58, 1-h conference calls with a number of members of each industry segment, plus additional calls with traceability solutions providers, trade associations, and others. Representatives from

Table 4—Description of various industry-led product tracing initiatives in the United States.

Industry	Initiatives	Features/status	Trade associations
Produce	Produce traceability initiative	GS1 128 bar code with GTIN and lot number	PMA, United Fresh Produce Assn. (UFPA), CPMA
Dairy	Limited pilot study	Exploratory	IDFA
Broad Spectrum Food Industry	Trade association traceability coalition	In discovery mode; expect more details after Sept 2009	10 to 13 trade associations led by FMI and GMA
Fresh Foods	Fresh Foods Initiative	GS1 128 bar code with GTIN, GLN, production date, and lot number	PMA, AMI, IDDBA, and others
Foodservice	Foodservice GS1 US Standards Initiative	GS1 128 bar code with GTIN and GLN (other elements to be included later; lot number and production date)	Intl. Foodservice Manufacturers Assn. (IFMA), IFDA, Natl. Rest. Assn.
Meat and Poultry	U.S. Meat and Poultry Traceability	GS1 128 bar code with GTIN, GLN, production date, and lot number	mpXML

Table 5—Distribution of food companies participating.

SECTOR	Firms represented in this study	Percentage	Industry profile
Distributors	3	5%	3000 (United States)
Feed/pet food	4	7%	500 AFIA members (United States)
Foodservice	10	17%	Approximately 1 million restaurants (United States)
Packaged consumer goods	8	14%	57000 food processors
Processed ingredients	4	7%	(No published data found)
Produce	22	38%	>10000 Blue book members (Int)
Retail	7	12%	Approximately 35000 with sales >$2 M (United States)
Total	58	100%	

very small through large companies were included in each segment. The number of companies participating for each segment is presented in Table 5. Not all firms provided the same level of detail, so subsequent tables conveying segment-specific practices may not include data from all firms participating. Participants were assured that their individual responses and company names would remain anonymous; however, they were offered the opportunity to "opt-in" to a participant list. This list is presented as Appendix G.

Although IFT efforts focused mainly on the produce sector, all other sectors were covered. It is important to note that with over 2 million farms in the United States (of which approximately 500000 grow food products), roughly 57000 food processors, nearly 1 million restaurants, and over 35000 grocery stores with annual sales > $2 million, the sample of participants in this task cannot be considered significant. Therefore, the information and conclusions presented are drawn from the conversations conducted and may not apply to each company or be fully representative of an industry segment.

8.1.1 General findings. IFT found challenges associated with each of the 3 main components critical to product tracing: accurate recording and storage of information on incoming products and ingredients (external tracing), tracing of ingredients and products within a facility (internal tracing), and accurate recording of information pertaining to products leaving a facility (external tracing). Given the nature of the information recorded at each of these points, it would be difficult to trace a product through the supply chain. Depending on the industry and the facility, the practices described in this section made linking the information pertaining to a specific product difficult or impossible.

Given the relatively small number of participants, the extent of commonality of key issues that complicate or prevent traceability observed across all sectors was striking. Appendix H presents the results of poll questions, and analysis of responses, that were asked during an IFT webcast on traceability in January 2009. Most traceability issues seemed to center around which data are recorded, the way in which data are captured, and the way data are exchanged within a facility and between trading partners. Overall, enormous variability in practices among the representatives of the different sectors of the food industry was observed, and these differences were often not correlated with product, facility size, and other important distinguishing factors.

Data recording—what is recorded. A lack of consistent or complete information on existing paperwork, including the lack of unique identifiers, hinders the depth and precision of product tracing. If documents such as invoices, bills of lading, purchase orders, or others are used, they often have dates, but may not have lot numbers or some other unique identifier, making the information often nontraceable, or at most, traceable 1 step back or forward only.

Frequently companies mentioned the lack of certain key definitions as a challenge. For example, in manufacturing, the definition of batch or lot may vary; in warehousing/distribution this term becomes convoluted with the assignment of internal "lot IDs" as described previously.

Throughout the course of this task we found that at times, incoming lot numbers, even if available, are not recorded for a variety of reasons including "I don't understand what they mean.", "There is no standardization.", and, "If I have a problem, I expect the supplier knows what he sent me." Many companies expressed a concern that having to read each lot number on a case could slow down production and there was the same concern with having to read lot information for products being shipped.

Many companies assign new internal "lot" numbers to materials received, and incoming lot numbers are often not linked with the newly assigned numbers. For example, if a pallet contained cases with different lots, the new number represented all lots (so it is impossible to differentiate between them). This practice was prevalent in all parts of the food industry—from ingredients being assigned a code by processed food manufacturers to warehouses and DCs identifying and selling items based on an item number. The way in which internal codes are assigned and level of sophistication ranged from handwritten records to bar codes to RFID tags. A uniform encoding system that begins at the grower level should eliminate the need for assigning new internal "lot" numbers; however, the practice may be hard to break. One distributor mentioned that even after the PTI is implemented, they will continue to use item numbers since they are part of their accounting system, and are the numbers used by customers to order products.

This task required the examination of tracing to the point of sale and point of service. Therefore, we considered the limitations and benefits to labeling and tracking individual items sold to the consumer. Currently, there is a lack of product labeling that allows the transfer of key data elements. Information that identifies the product may be on paperwork but not on the product itself (although the availability of lot numbers on processed, packaged foods was high). Moreover, small packages may not have available label space and products such as loose produce are often sold without a label, so their ability to be traced back is lost at the point of sale. Even if information was available on the individual consumer item, retail outlets cannot currently capture lot-specific information during transactions with customers.

Data capture—the way in which data are recorded. The data elements shared between trading partners vary from company to company. Since the expression of information on paperwork is not standardized, acceptance by electronic systems, especially those used by trading partners who may not be able to decipher or interpret the information, is difficult. Some data elements are machine or computer generated, and others are handwritten on documents. Without the use of consistent standardized data elements that must be recorded, the type of information that is ultimately captured is unable to pinpoint a particular product's movement or characteristic and is lacking in precision.

IFT found a prevalence of companies who use paper documents to record information, rather than electronic records. Many companies also use a mixture of both paper and electronic recordkeeping. Concerns with paper records include accuracy (transposition of numbers and other human errors) and the lack of speed (cannot query; difficult to manually record information legibly in high throughput operations). Costs associated with electronic systems were often cited as a key concern and perhaps a reason why more companies do not use this form of recordkeeping. Companies IFT spoke to mentioned the cost of changing information technology (IT) systems, training people and purchasing hardware, and of "slowing down" an operation to switch to new software or to capture or provide additional information. Details can be found in section "Barriers to Implementation" and in the Economics Report (Volume 2).

Data exchange. Within companies, multiple electronic systems may be used that often cannot communicate (batching compared with warehouse management systems [WMS] compared with accounting systems). Furthermore, there were often no links between information received and shipped from facilities, causing a lack of internal tracing at companies.

Electronic systems were found to often have limited interoperability, prohibiting internal and external tracing. Legacy systems are prevalent, especially for large manufacturers who have acquired many companies/facilities. Custom systems that are designed in-house, often at large companies, are also prevalent. Making modifications to "off the shelf" systems is expensive so many companies avoid this route.

It was clearly conveyed that companies feel they are responsible for 1-step forward, 1-step back records, and that they are not responsible for knowing who supplied their supplier, or who bought from their customer. They clearly expect that their suppliers and customers (respectively) also keep 1-step forward, 1-step back or beyond records and therefore know where the product came from and went to.

There are several ways that trading partners communicate with each other and exchange information. Many use electronic methods, such as advance shipping notices (ASN). Third party systems are also used to conduct business transactions. Although these systems exist, they are seldom used to transfer data elements important for product tracing, such as lot. Instead, the purpose of ASN is inventory control, and financial transactions aid in accounting. However, it seems that these systems can be used to exchange additional information.

Accuracy of records. Quality of data, such as accuracy due to falsification of information to meet requirements/quotas and readability, may also be issues. When individuals were asked about accuracy of records, it was clear that manual entry of information could cause errors. Since manual capture of data is very common for all sectors interviewed, the potential for human error is high. For example, a bilingual workforce could potentially transpose month and day due to cultural differences. While Americans typically think 01/02/09 means January 2, 2009, people from Latin America, Europe and other regions in the world may interpret this as February 1, 2009. This lack of international uniformity in date expression can result in inadvertent "changes" in shipments out of first in, first out (FIFO) and may alter data capture and/or recording.

It was difficult for most individuals to quantify inaccuracy of records, but when a number was offered, it was typically around a 5% error rate. These errors ranged from transposing dates, to incorrect country of origin, to incorrect identification of a product. Companies were quick to point out that they check for these types of errors and require prompt correction (or else they reject a shipment) on incoming products/ingredients.

FIFO was often used for shipping in various segments of the food industry, such as distribution. FIFO is not a reliable system, especially for produce, because although it is generally adhered to as a default, sometimes customers know there is fresher product and insist on it, so that there is "lot jumping." However, FIFO is specifically not used in repacking operations.

Other common issues. There seems to be a lack of understanding of the core elements of a product tracing system, and education around this issue might be useful. There is also concern over who the legal owner of data is and who is responsible for providing the data to FDA in the case of a request. The BT Act limits FDA's ability to review records to verify that they are kept, and companies also noted FDA's lack of enforcement authority in foreign countries. Enforcement of the current recordkeeping requirements is an issue, as evidenced by the following testimony Tom Stenzel, of the United Fresh Produce Assn. gave to the U.S. House of Representatives: "We know of no instances where FDA has taken any regulatory action to cite a produce company or its customers for failure to provide adequate records as required by the Act." . . . "I recommend that we urge FDA to enforce the current law before we all call it a failure. If in an outbreak situation FDA finds companies not in compliance, then take action. Take highly visible action. That's what signals the importance of proper behavior to those in any industry who might be inclined to cut corners. And, if FDA needs additional authority to ensure that companies are in compliance before an outbreak, that should be part of the solution" (Stenzel 2009).

There is no standardized format for product tracing information to be communicated between trading partners or submitted to FDA which increases the lack of interoperability between various systems and records trade partners may use. This, in turn, increases the amount of time it takes to sort through various forms of information to find what is most useful during the course of a traceback investigation. It would be helpful for many companies to know exactly what information is most useful to FDA and other regulatory authorities, and therefore what they should focus on recording.

Small operators may have limited infrastructure (for example, no IT staff) to record and manage data electronically. They are also more likely to have cash transactions and may not keep detailed records of these transactions. They are also more likely (especially, foodservice and retail) to shop at membership stores, such as Costco and Sam's Club, to add to their own supply which limits their 1-step back records.

Those who conduct mock recalls told us that could trace product in a relatively short period of time (typically minutes to hours). This is much more rapid than what is often observed during a traceback investigation. Upon further probing, and as a result of input from the food industry subpanel, it became clear that the "minutes to hours" estimate, although true, did not always represent the complete practices that were followed when a regulatory authority requested information. A few companies reported that they would locate and secure paper forms of documentation to verify what the electronic trace told them (in the minutes to hours time frame). This "double check" took substantially more time.

Practices, issues, and other findings specific to each segment of the food industry interviewed are outlined below.

8.2 Animal feed

Much of this industry is vertically integrated, where those producing feed are using it to feed their own animals. In these instances, they are exempt from the BT Act. For the portion that provides feed commercially, the majority of feed is provided by a few large feed mills. Roughly 20% of all feed companies likely control 80% of the feed industry. About 45% of feed companies are registered with FDA.

The feed industry has found that there is strong interest from customers in feed safety (ex. bovine spongiform encephalopathy [BSE] free), but not a strong interest in product tracing, although it does help to assure safety. A feed association implemented the Safe Food, Safe Feed Certification program, which has a traceability component, and they currently have 350 certified companies, which represents over half of their membership. This program includes a new amendment that product coming from suppliers must have a product lot code and be sealed. The size of a lot is not defined by the Safe Food, Safe Feed program, but participants are required to record product lot codes, if they are available.

A product tracing issue for feed companies is their prevalent use of bulk ingredients. Feed companies are unable to trace lots of bulk ingredients, like grains, that they use. Although they do maintain records from cleaning-to-cleaning and know what new lots went into a silo during that time frame, they do not distinguish between outgoing lots. Also, each silos unloading rate is dependent on flow, and thus it varies for each ingredient and between vendors. One cannot assume that each bin is unloaded at an even rate, as that is not always the case. Feed companies often use several suppliers for each ingredient which can create a complex traceback for the FDA in the case of a contaminated bulk ingredient.

The one pet food company who participated did not appear to use the high number or large volume of bulk ingredients that the livestock feed industry uses, although they still used some bulk ingredients and still used many ingredient suppliers. Since this industry segment was not a priority, there are insufficient data to characterize the sector. However, pet food production is in many ways similar to the production of other processed foods.

8.3 Produce

More effort went toward examining the produce supply chain compared to other sectors for this task. The time from the beginning of the patient's illness to the confirmation that he or she was part of an outbreak is typically about 2 to 3 wk (CDC 2008).This exceeds the shelf life of many produce products, so that the original packages or cases have likely already been discarded. United Fresh estimates that 6 billion cartons of fresh produce are shipped in the United States annually. Fresh produce is usually divided into 3 categories: packaged products (such as salads) with UPC codes; bulk produce in its original carton; and bulk produce that is repacked and may be commingled with other lots for product quality (Stenzel 2009). The number of different types of produce is high, and within each product, there may be different ways to grow, harvest, process, and transport products. Figure 1 shows the variety of paths a product may take on the way to the retail market.

IFT sorted the produce industry practices based on their part of the supply chain: grower, processor, or warehouse/distributor. However, we were able to draw some general conclusions when looking at produce in totality. Table 6 and 7 summarize the main findings for growers and processors in this sector.

Similar to other segments, most produce companies expressed frustration in the current lack of consistent standards, which obligates them to handle and generate multiple forms of information simultaneously. The lack of a unified standard on the data requirements by customers was considered to hinder their operations significantly. In particular, processors who packed for private labels and also had their own brand put different types of information on product packages and cartons depending on customer requirements, even though the product was the same. Also, there is a lack of standardization in names for varieties of a single product, which creates duplication of identifiers or descriptors for a specific product. However, the United Nations Standard Product and Services Code (UNSPSC), which is a globally used classification system to organize and manage information on a wide variety of products and services, includes classification of fresh produce. Additional details are provided in section "Globally Recognized Standards."

Some produce growers are using tools marketed by solutions providers that are designed to explain the path food takes from the farm to the grocery store, which they say will boost consumer confidence in its safety. However, one grower that began using this system reported push back from retailers who feared that consumers may view product as "old" if they could view the harvest date. Concerns over facility security (by providing growing locations) were also noted. Overall, most companies expressed the lack of interest by suppliers (growers) or final consumers for a traceability system, thus a competitive advantage in the implementation of a system was not observed in all cases.

Additional costs were also perceived as a barrier to implementation, since companies consider their margins would be lowered even further after the implementation of a product tracing system. However, few were able to even estimate the costs to enhance traceability, other than relating it to the PTI. Like other sectors, there was great concern over who would absorb the cost associated with product tracing.

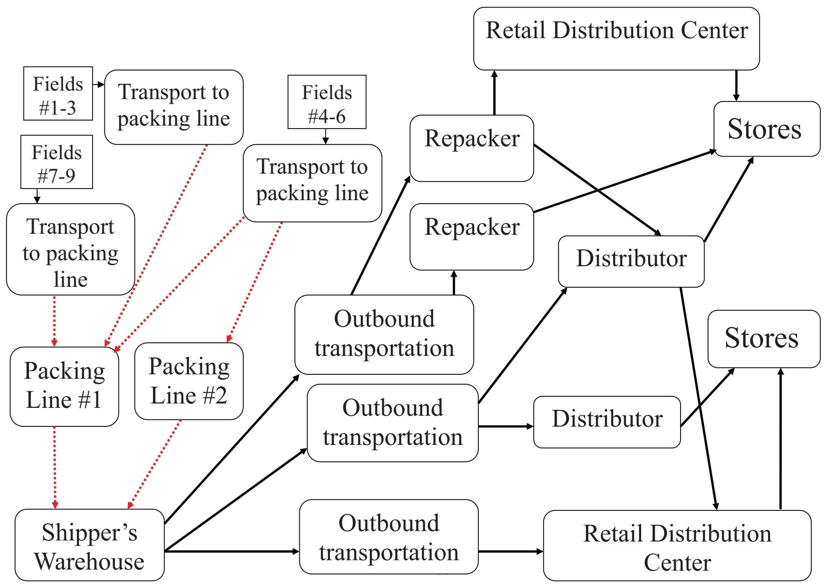

Figure 1 – Potential pathway of produce to retail stores.

Table 6 – Main practices for produce sector: growers.

Current practices	Number ($n = 5$)
Identification at field level	
Use fully electronic system (for example, apply/scan bar codes)	3
Manually records data; entered to electronic database	1
None	1
Outgoing product labeling	
Case level	3
Pallet level (only)	1
None	1
Lot number conveyed to customer	
Yes	2
No, but know from internal shipping records	2
No, but can estimate from ship date	2

Table 7 – Main practices for produce sector: fresh-cut processors.

Current practices	Number ($n = 10$)
Have electronic database	6
Both manual and automated data input to electronic system	4
Manual recording of data only	6
Require incoming supplier lot number	5
Assign new internal lot number	9
Internal lot number based on shipment	4
Internal lot number based on date	2
Internal lot number based on pallet	2
Internal lot number based on case	2
Internal lot number applied as bar code	3[a]
Assign outgoing lot number different from internal lot number	8
Have experienced recalls	8
Mock recalls in place	6

[a]An additional company applied bar codes to lettuce only.

A portion of the produce industry is in a state of transition and actively changing their current systems due to the PTI. Although IFT did not evaluate the PTI, it was mentioned by various company representatives in the produce industry, particularly at the grower level, which was expected, since they are the first to be affected by this self-imposed industry standard. IFT found it useful to discuss the PTI, since it exemplifies the challenges associated with spreading accurate information regarding requirements. Not all companies interviewed were aware of the PTI, and although most were aware of the initiative to some extent, what they understood regarding details varied. Additional details on the PTI can be found in Table 4.

Another regulation, country of origin labeling (COOL), has had a significant impact on the produce industry. Although most companies claim that cases are labeled with country of origin, some felt that information was not always accurate, and several reported occasional experiences where the country of origin listed on a bill of lading did not match the shipment. However, there is recognition that COOL information is not stored for product tracing purposes but rather for marketing purposes. COOL is required at retail, but not at foodservice. On a few occasions, when talking to those who serviced primarily foodservice, the relative importance of COOL was minimal. In the context of COOL and traceability, the lack of coordination and a unified message from regulatory agencies was also expressed as a barrier to implementation, since each time new regulations requiring additional data capabilities are published, system enhancements and updates are needed. Companies expressed a strong preference for one system, with all requirements known up front, that would not require frequent updates.

In terms of the way in which produce companies capture information, this, again, is in a state of transition as the industry moves from a hodgepodge of methods to the bar code mandated by the PTI. Currently, not all companies interviewed were able to store information electronically and hence their ability to trace a particular product back or forward was very limited. Moreover, companies were not able to trace more than 1 step backwards or forward, thus the depth of all the systems companies use is limited (and this will not change after the PTI is fully implemented).

Although the majority of produce companies have an electronic system that is able to record and store information, data input was done manually for more than half the companies we spoke to, which could be a significant source of error. Even in some cases when electronic information was automatically input into the systems (for example, scanning bar codes), additional manual information was added as well lowering the precision of a full electronic system.

Most companies assign an internal lot number to all their products at the pallet level, either manually or through a database. Some companies use the internal number throughout their operations and it serves as the outbound "lot number." We found that companies consistently assign a new number (even if it is only a "use by" date) if the product changes through packaging or minimal processing, although in many cases the links to the incoming lots are difficult to firmly establish. For processors, lot numbers are usually assigned based on the customer requirements for the product that is delivered to their facilities. Thus, companies assign numbers in accordance to customers' standards. Given the variability of systems observed across sectors, companies may handle multiple numbers that correspond to the same product depending on the requirements of their customer, which also could be a source for error.

8.3.1 On farm. In the field, workers may be paid by the piece and not on an hourly basis. High throughput has greater value for the worker, and there is an economic disincentive to slow down the process for recordkeeping purposes. Stickers or other tags are either filled out by hand or generated by label makers and applied to cases of freshly picked produce. Common data elements seem to be harvest date and crew, and there is also generally a lot number that links to the agricultural inputs for the field.

Information that differentiates each lot (field, orchard, and so on), may be lost during normal handling or shipping due to various factors or practices: commingling during washing or processing, lack of adherent labels to wax boxes (especially when there is washing/temperature change), and so on.

An expressed weakness of a manual system at the field for produce relied on the human element, and the opportunity to forge information. This might be done to meet yield projections or internal productivity standards (for example, if the production of one crew is low and another is high, records may be adjusted so that they appear more even). This practice would provide a major obstacle to traceability. The readability of handwritten information may also present challenges to the next recipient in the supply chain. Often, the information from the tag is entered into an electronic system via data entry.

There are currently no firms that we spoke to or heard of that are labeling individual bulk products displayed with traceability information. In addition to the difficulties and time it would take to apply this information to individual, whole pieces of produce, we also heard that it is currently difficult or impossible to properly label cases with the contents. In other words, the case label would not be able to represent all the unique pieces of produce in the case. Packaged products (those that have a wrapper or clamshell) can be more easily labeled with information that provides traceability. Products that can be packed in the field (for example, strawberries) can more easily have traceability information applied, since their form does not change throughout the supply chain. However, retailers do not currently capture the unique tracking numbers at checkout, and because produce is perishable, it can be reasonably expected that the packaging will be gone by the time an investigation commences.

8.3.2 Fresh-cut processors. Fresh-cut products such as bagged salads, chopped vegetables, and cut fruits have increased in prevalence due to the ease of use by consumers and foodservice operators. In these operations, one or more items are commingled and may be chopped or otherwise processed, and packed into bags or other kinds of containers. As mentioned previously, although the package that reaches the consumer may have a "use by" date or other information that relates to lot, the package may be gone by the time a traceback investigation begins. Therefore, we will focus our analysis on other aspects of fresh-cut processing that relate to traceability at the case level.

Fresh-cut processors usually received product direct from a grower, although in some cases brokers, distributors, and terminal markets were used to supplement what was purchased directly. In some cases, a 3rd party program was used to procure all or some of the product. This was also observed in the wholesaler/distributor segment as well as in retail (for produce). These systems link sellers and buyers, but lot specific information is not usually communicated through the transaction.

The vast majority of fresh-cut processors assign an internal lot number to incoming produce. Many of these internal "lot numbers" were assigned based on the purchase order, and some were specific only to the truck that transported the shipment. One firm acknowledged that this was a major gap in traceability, but that they were waiting for the implementation of the PTI before they would begin to capture more discrete data. Some required a unique incoming number, but did not specify how it was assigned. In many cases, the new internal number is computer generated or simply the Julian date of receipt.

In the case of bagged salad, one firm (who had a recall associated with fresh-cut lettuce) applied bar codes to bins of lettuce, and then scanned them as they were used for processing. In another firm, the bins of lettuce had a printed "lot number," and the operator hand wrote the information from each bin before adding it to the processing line. The volume and throughput was such that lettuce from multiple bins could be combined in one outgoing bag. It was observed that this happened for other types of products as well.

Packaged product often contained a "use by" or "best by" date that could easily be tied back to the production date. The inputs for production are less clear, since many relied on FIFO (using the applied Julian date). Also some fresh-cut processors served as wholesalers of loose produce, and then, relied on shipping records and a back calculation to determine when the product was likely received, and deduced who the "1-back" supplier was.

Many fresh-cut processors sell to retail and foodservice, many pack for private labels and still others have their own brands. One private label packer, who could not be identified by the information printed on the consumer-level package, stated that he knew he was the only source of that particular item, and felt comfortable that the retailer would know to contact him if there was a problem with the product.

One area in which product tracing could be improved in this segment would be by requiring suppliers to provide lot numbers, and record those incoming lot numbers. Regardless of whether or not the assignment of an internal number persists, the specific produce used in processing must be captured (for example, either the internal number or supplier-provided number should be recorded when it enters the process).

8.3.3 Produce wholesalers and distributors (including terminal markets). As part of this task, IFT staff visited vendors at 3 terminal markets: Baltimore, Chicago, and Los Angeles. Terminal markets for produce exist in most major cities, and cities may also have multiple terminal markets (often "new" and "old"). "New" facilities were visited in Baltimore and Chicago. In Los Angeles, both old and new markets were toured. Each market consists of a number of different wholesalers selling a variety of produce items, generally by the case, but possibly as partial cases.

Generally, buyers at terminal markets are small restaurants, catering companies, and independent or small retailers. However, it was found that some terminal markets are also open to the general public. Additionally, some small regional distributors purchased product at such markets for their restaurant customers. Also, a fresh-cut processor was interviewed, who found it most efficient to purchase items that were used in small quantities from the market.

New terminal markets toured were similar to other modern markets. There was a limited amount of product on display; most was in a temperature-controlled warehouse. Some vendors in new facilities did limited repacking for quality by removing spoiled or defective product. On the contrary, in the case of "old" facilities all products were on display. Also, many vendors in this type of terminal market deal in cash only.

Product at terminal markets comes from a variety of sources, and may include direct and indirect paths. Product may come from growers or other distributors, or may be "rejects" from retail, or "leftovers" from an already harvested field due to marketing restrictions that limit amounts of product to be harvested or sold. Some of these practices may disrupt the chain of custody of certain products since their source is not traceable. In the cases of cash transactions, if additional records are not kept, the lack of credit card slips could prevent the trace of information forward in the supply chain. In some cases, produce was sold "loose" or without packaging. Thus, its information from the original packing is lost preventing any possible traceback or forward related to that specific product. Repacking on site was evident, and boxes were clearly reused in one location. This practice may mix product and boxes, and thus cause loss or misinterpretation of information related to original source and products' path through the distribution system.

Of the 5 wholesalers/distributors who provided information for this task, four assigned an internal lot number. One, a small distributor to restaurants, kept no information, and discarded receipts when invoices were paid each week. When an internal lot number was assigned, the granularity ranged from the level of a purchase order number (least granular) to the pallet level (and further, if the pallet was found to have multiple incoming lots). In only 1 case was the one-to-one ratio of incoming to outgoing lots maintained.

In some cases, internal lot numbers were tracked using bar codes, which were scanned when pallets were moved or when cases from within the pallet were shipped. In other cases, the numbers were computer generated and stored electronically; in others, they were tracked using a paper-based system.

All firms reported shipping based on FIFO, but 2 specifically mentioned the ability to bypass this system based on customer requests. In only 1 firm was the internal lot number provided to the purchasing customer. Other companies reported that this information is tracked but not made readily available to the customer. In the latter case, one firm can identify the internal lots that shipped electronically; another firm would find this information in a paper system.

It was found that in general, traceability challenges are vendor dependent. In many instances, however, it would be very difficult to trace a product in this segment of the industry. Some products arrive through convoluted pathways that are not always evident, and there are no records that would allow their path to be traced through the chain of custody. Based on the small sample, it seems that internal traceability is lacking, since incoming lots are not linked to outgoing lots in a one-to-one relationship by most produce wholesalers/distributors. However, since most cases are unopened by members of this supply chain segment, and commingling of product generally does not occur, it seems that product tracing in this segment can be improved through changes in recordkeeping.

Product Tracing for Imported Produce and Other Imported and Exported Food Products Worthy of mention are the assorted comments pertaining to imports and exports. Some participants felt that the standards for imported products were greater than those for domestically produced, while others felt that cultural differences and a lack of regulatory control in some countries could compromise the safety and traceability of imports. Other firms mentioned that products that are exported require different kinds of information, that relate to traceability.

Fresh fruit and vegetable imports to the United States have been growing steadily over the past decade. One produce company IFT spoke to who is located in Mexico pointed out that there are stricter regulations on products imported into the United States, compared to products grown in the United States. It was his opinion that all the required information makes imported products easier to trace than some products grown in the United States.

The safety of U.S. food imported to our country is safeguarded through premarket clearances, mandatory production practices, inspections, and random ongoing sampling. The food safety standards that apply to domestically produced foods also apply to imported foods. If the label of a food bears statements or symbols in a foreign language, the label must bear all the required statements in English as well. All imported fruits and vegetables must also be marked with the English name of the country of origin. Importers must determine rules and regulations and procure import permits to import their specific product into the United States. USDA Animal and Plant Health Inspection Service (APHIS) and Agricultural Marketing Service (AMS) and U.S. Customs Service may have specific requirements for fruits and vegetables. The USDA has a Fruits and Vegetables Import Requirements (FAVIR) database which references fruits and vegetables that have been authorized entry, and allows users to search for authorized fruits and vegetables by commodity or country, and lists the requirements for importation to the United States. Requirements differ for each fruit and vegetable.

Importers must file an entry notice with the U.S. Customs Service and submit necessary permits to APHIS for review and inspections. Imported goods may not enter the U.S. legally until delivery has been authorized by Customs. Not all federal agencies inspect product, but they all must grant release for the products they have jurisdiction over. APHIS may inspect approved and permitted goods for phytosanitary certificate to ensure fresh fruits and vegetables from other countries do not introduce plant pests or diseases, AMS may inspect applicable produce to ensure it meets import requirements relating to grade, size, quality, and maturity, and FDA may test products entering the United States for compliance with Environmental Protection Agency (EPA) regulations for pesticide, fungicide, and herbicide residues. If produce is found admissible and duties are paid, it is released by Customs and passed into the United States.

Requirements for avocados, for example, include that they may be imported into and distributed in all U.S. states, but not U.S. territories. They must originate from one of several municipalities in Mexico; must arrive with seals that match the phytosanitary certificate and have a phytosanitary certificate with declaration that, "The avocados in this consignment meet the requirement of 7CFR 319.56-30." They must be packed in clean, new boxes, or clean plastic reusable crates. The boxes or crates must be clearly marked with the identity of the grower, packinghouse, and exporter and they are subject to inspection. There are many other potential requirements as well, such as the need for the orchard and grower to be registered with the Mexican NPPO's avocado export program and listed as an approved orchard or grower.

While there are specific regulations pertaining to imported products that some might argue provide enhanced traceability compared to those produced domestically, concerns related to the traceability of imported goods were also shared. Specifically, it was suggested that in some parts of the world, it is considered an insult to ask for paper documentation and verification, since this is perceived as a lack of trust. In these areas, there may be secrecy and competition such that the physical location manufacturing, for example, a food ingredient, may not be known or may be misrepresented by the seller to the buyer. Clearly, providing false information related to the production of materials will prevent traceability. The implementation and enforcement of international regulations, including audits by buyers, may be needed to ensure that traceability across U.S. borders is possible.

Some firms also noted the import requirements of other countries. Japan was cited as a country that "wants to know everything." This reinforces our sense that, in order for companies to compete fairly in a global marketplace, global standards should be developed.

8.4 Ingredients

Compared to the pharmaceutical industry, which typically has one or very few "active" ingredients (with the remainder often serving as excipients), the use and variety of ingredients in the food industry are quite broad, and the resulting foods more complex. As the PCA associated Salmonellosis outbreak showed, ingredients may follow multiple distribution paths, and may be combined with other ingredients before being used in a final product. Therefore, the ability to trace ingredients backward and forward is critical.

Ingredient suppliers received their starting materials from a variety of sources: some had relationships with the growers of raw agricultural inputs, some used broadline distributors for minor ingredients that they further combined, and some used independent companies to produce the ingredients branded under their name.

All companies IFT spoke with were able to store information electronically and hence their ability to trace back or forward was facilitated. This ability was not related to the number of stock keeping units (SKUs) they produce. Most ingredient suppliers are aware of where their ingredient is shipped to and most can determine this within a matter of minutes. However, they do not know where the ingredient is distributed to beyond that 1 point, such as retail locations, or what finished products it goes into. Not all companies were able to trace more than 1 step back or forward, although some, which were vertically integrated through the farm level, could trace back fully. Not all companies were able to link their information through their business units, particularly for large companies with multiple facilities who had many acquisitions. Thus, information was siloed per facility in some cases. In both larger and smaller companies, different information resided in different systems within the same facility, such as shipping, accounting, and production systems. Even though they are all electronic, the "link" needs to be done manually. These practices limit the depth of all their systems, which otherwise are fully functional.

The information associated with incoming material, and its format, varied by company. One company required that lot numbers appear on invoices, and that lot numbers be communicated to the corporate office prior to the material arriving at the warehouse. Two reported that cases were required to have specific information, including the product code (for example, item number) and lot number (as assigned by the sender). Data input was done manually by some of the companies. Even in cases when electronic information was automatically entered (scanned), additional information was manually added lowering the precision of a full electronic system. This practice could subsequently be a source of error.

More than other sectors, representatives from this sector noted other requirements, often from other agencies, that, depending on one's perspective, could enhance product tracing or make the management of multiple forms of data more complex. For example, one firm reported that incoming raw materials have 15 associated documents linked to them in their system, including bill of lading, invoice, truck affidavits, certificates of analysis, and so on. Another reported state-level requirements at the farm level, which required the firm to cross reference the 4 ways a field is identified.

Since in most cases, these products require some transformation, and may incorporate other ingredients, companies often assign an internal lot number to all their products at the pallet level, either manually or through a database. One company used RFID tags to follow inputs through production, and this was done to identify operational inefficiencies. Alerts were built in, for example, if an operator tried to use a nonorganic ingredient in a formulation for an organic product, it would beep an error upon scanning. For inputs that have high throughput rates, a FIFO system may be used. To identify the components of the end ingredient, one would take the "hold time" into consideration and be able to deduce the inputs. This theoretical estimate is subject to substantial error if any deviation from the normal process is experienced, since internal traceability is not explicitly maintained.

A nuance of the ingredient industry is the multitude of customers they have. In addition to selling ingredients to other food companies (for incorporation into further processed foods), two of the companies we spoke with sold directly to consumers through retail, and many had considerable business with the foodservice sector. With the exception of one firm, the outgoing lot number varied depending on the customer, and also depended on the segment to which the customer belonged. Cost of implementation was expressed to be the main hurdle for this sector's product tracing efforts since they are obligated to comply with the variation in data and information requirements given by all customers these companies trade with.

With respect to the way information is communicated on outgoing ingredients, one company reported that customers are requesting bar codes, but the company feared that they would have less control of the accuracy of information if bar codes were used compared to the printed label that they currently use. Another used bar codes on most products, and was looking into RFID at the trailer-level for bulk ingredients, but noted that this was being explored for efficiency, not product tracing.

The production schedule had a bearing on product tracing for some firms. One company, who processes raw agricultural products that are only available seasonally, reported that each individual ingredient is only processed for a few days during the entire year. Since production is fairly isolated, the point of production and ingredients used are known. However, it should be recognized that the few days worth of production may be sold and enter distribution for the remainder of the year, making trace forward more complex.

Most firms have encountered recalls in their operations, and have implemented crisis management teams as well as food safety groups. These groups were typically the ones responsible for managing product tracing.

The packaging size for ingredients may be more variable than some other segments of the food industry. For example, some dry goods such as flour may be bagged, and the bags may be banded together. Adhering a label in this instance is not as simple as it is for a cardboard case. In other instances, ingredients are shipped in bulk, and then the level of identification may lie at the tanker or railcar.

Ingredients frequently arrive in very large volumes or bulk. It was observed that product tracing for bulk ingredients such as grains, or fluids was very difficult, since facilities could only estimate the number of suppliers involved in a given silo or tank via mass balance. Below is a more detailed description of these types of ingredients and their implications on product tracing.

8.4.1 Bulk ingredients. Bulk ingredients represent a certain segment of the food industry for which product tracing is more complicated. Products that are held in silos, such as flour, milk, oils, liquid sweeteners, and so on are from multiple sources, such as milk from multiple farms, with multiple cows per farm. It may be appropriate to view bulk ingredients similarly to processed foods: they represent a many-to-one relationship with many inputs (such as different fields of soybeans) being combined and processed to yield one product (crude soy oil). Traceability may appear to be difficult in these types of operations, since it is not possible to trace back to a single source. It was found that handlers of bulk ingredients do keep records and track ingredient inputs into silos. Thus, the quantity of product per "lot" becomes very large (for example, a silo) but its source could be traced back with some precision. Some granularity can be achieved in bulk systems through engineering calculations. Some companies, particularly those manufacturing or using dry products, report that they can calculate throughput rates and have reasonable confidence that a specific percentage of incoming product has been emptied from the silo at a specific point in time. One tomato processor reported that due to commingling, any product was likely to contain tomatoes from 3 to 8 fields. The frequency of cleaning varies depending on the type of product held in the silo, and cleaning does represent a clear break. Still, for some products, production may only stop once per year.

The unit size of bulk ingredients makes them more difficult to identify. In some cases, RFID tags were being explored for use on tanker trucks, but that was being done for efficiency. One firm reported that bulk materials are brought in via railcars, and that the transaction document specifies the contents of each railcar; however, the bill of lading has only 1 unique identifier. When railcars were used to ship outgoing materials, railcars might have bar codes, but that was for tracking the movement of the railcars, and not the contents. Additionally, some firms receive bulk ingredients that are pumped directly to the plant from a neighboring facility. In this case, time windows may be specified, but there is nothing to physically label.

It should also be recognized that, given the volume of silos, contaminants may be diluted to a concentration that makes them less likely to cause harm. Bulk ingredients are also more likely to be further processed, decreasing their likelihood of serving as vehicles of microbial contamination.

Bulk Milk Traceability Pilot The U.S. Dept. of Homeland Security (DHS) has given increased attention to bulk food because it poses a high-consequence health threat to our society if intentionally or unintentionally contaminated. A pilot began in 2006 to investigate bulk milk and a multidisciplinary team with the Univ. of Kentucky's Div. of Dairy and Ag Regional Milk Specialists developed a comprehensive milk transport security and product tracing system. Current methods used for securing bulk milk during transport are labor and paper intensive, thus, complications associated with handwritten records can occur and traceability programs making use of these records may be cumbersome. This pilot examined the development of a bulk milk transport security system designed to improve food safety and defense protocols while facilitating the collection of operational information. This development project has resulted in a comprehensive system that enhances the ability to trace raw farm milk, improves operational efficiencies, and strengthens security for the dairy industry. While the system is dairy sector specific, it has a broad range of potential applications relevant to other bulk liquid food products.

For the pilot study on bulk milk product tracing, 15000 delivery trucks were fitted with sensors with a handheld device provided to drivers, at a cost of $8000 per vehicle. At the farm, drivers scanned their ID and entered a pin code on the devices that tracked their GPS coordinates. They scanned the farm's bar code, and truck sensors monitored opening the doors and pumping the milk. Then, when delivering the milk, drivers were required to log-in and scan their bar codes. In near real time, their handheld devices contacted the home-base servers and the data were stored.

In the study, a list of all the farms feeding into the silo could be obtained in seconds. In the case of a recall, it would be possible to trace bulk milk 1-step forward and back, including the equipment and personnel that handled each silo/tanker of milk. This methodology could be applied to other agricultural commodities as well and cell phones and other communication methods could be used as scanners. Dairy delivery drivers were agreeable to the concept, particularly those from larger companies and international milk haulers.

Currently, the dairy industry uses bar codes and identifies drivers. In the project, milk is still commingled in the tankers, making tracing of individual lots nearly impossible. In the future, modern dairy farms may be able to wirelessly extract individual cows' data (such as birth date and location) to provide a more detailed level of traceability, although they are not close to this level currently. Those coordinating the pilot felt that ideally, there would be 1 data server for the entire United States; however, some dairy co-ops do not want their data shared with others. In these cases, such farms could have their own servers, though there would be a loss of traceability when the information is not centralized. It is complicated to send data to multiple servers for 1 truck, receiving milk from many farms. Privacy would be a chief consideration, with individual companies authorizing who can view their information, and the FDA only being granted access in special instances, such as an animal disease outbreak. Work is currently underway to launch a commercial-ready system.

8.5 Packaged foods

Packaged foods are generally processed products that are provided to the consumer either directly through retail outlets (via distributors or direct-to-store delivery) or are provided to foodservice operations. Almost all participating companies were able to store information electronically (Figure 2). Hence, their ability to trace inventory back or forward was not limited by their ability to store historical data. Not all companies were able to trace more than 1 step back or forward, thus the depth of all the systems currently in place is somewhat limited. Also, data entry was done manually for a couple of the companies. Even when electronic information was automatically input into systems, additional information had to be entered manually for systems to be

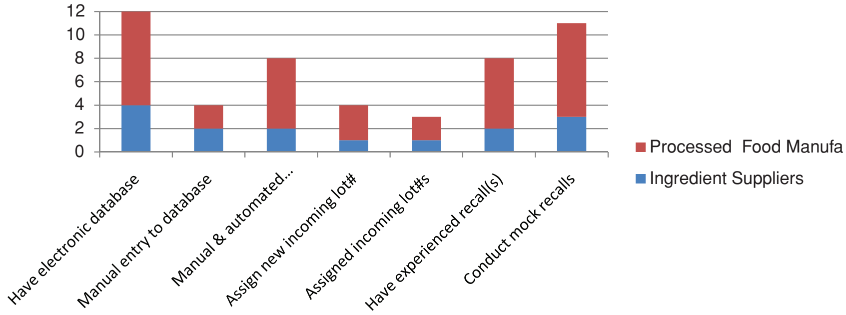

Figure 2—Practices and experiences in the ingredient and packaged food segments.

functional. This practice lowered the precision of a full electronic system, which could subsequently be a source of error.

All firms in this segment require that incoming ingredients be identified with a unique identifier, which is generally a lot code or in some cases, a harvest date. One firm required that incoming ingredients be labeled with a lot identifier, but this could be unique anywhere from the pallet to the case level. Thus the definition of a "lot" was not specified, although the number of different "lots" per shipment was restricted. Another requested, but did not require, that a "lot" change after 24 h of production. Yet another noted that although lot numbers were required, it was observed that some did not change frequently. Within this segment, information could be conveyed in any format; bar codes were required by only 1 company. In addition to the 1 company that required bar codes, 2 companies would scan bar codes, if present; another did not; and yet another would transcribe bar code information by hand and enter it into a database.

In terms of procuring ingredients, many firms receive ingredients directly from the manufacturer, although some use brokers as well. One company reported trying to reduce the number of suppliers shipping them the same ingredient, as well as moving toward consolidating the number of suppliers so that one supplier would ship multiple ingredients.

Larger food processors may be able to impose their standards on ingredients companies, especially if they are medium or small enterprises, and some require their suppliers to code ingredients using a specific format. In this case, the supplier was still required to provide a unique identifier (for example, a lot number).

Since ingredients are usually processed into new products, many companies in this sector assign a unique internal lot number to all their products at the pallet or case level, either manually or through a database; however, three used the vendor-supplied lot number. One firm was moving toward a system whereby the vendor lot number and date of manufacture would be captured, and a bar code would be generated and applied to the case. Another reported that most plants still applied a handwritten warehouse tag, although a few plants had the ability to use a more automated system.

The knowledge of which ingredient is used in a particular finished product may be handled through a batching system. This can aid in product tracing if lot numbers of ingredients are associated with specific batches. Several firms we spoke to in this segment use SAP (a comprehensive range of enterprise software applications and collaborative business software), which is discussed in greater detail when "electronic systems" are discussed (section "Electronic Systems"). To address internal traceability, this sector commonly uses mass balance to estimate the amounts of ingredients that are used in their products and their source. As in the ingredients sector, these companies use calculations to estimate ingredient quantities that are used, based on the quantities left and mass and energy balances. Thus, they are not able to definitively determine, but only estimate the ingredient lots that were used in specific lots of finished product. One firm did require each batch operator to record the lot number of each ingredient that was used in each batch, and this information was entered into a database daily. Another both scanned the (internally applied) bar code for the pallet, and had the batch operator manually write the lot number used in each batch, and reconciled these figures at the end of each day. The firm that required bar codes on incoming ingredients simply scanned those ingredients as they were to be used in a batch.

One retailer who has strong private label sales reported that during the PCA peanut paste outbreak, the firm was able to electronically search product names containing the term "peanut butter," however, they could not search by ingredients. Therefore, they had to contact the Research and Development team to manually determine products in which peanut paste was used as an ingredient. This substantially hinders product tracing.

Rework is quite common in the processed foods industry. Many products are rejected for quality or other reasons, but are salvageable and reused in the manufacture of subsequent batches of product. This practice complicates but does not necessarily prevent product tracing. In most cases, rework is assigned a unique number and tracked as an ingredient, either automatically through a batching system or manually. Many companies limit the amount of rework that can go into a new product to 5% to 10%. This means that 1 batch of rework could be an ingredient in 10 to 20 batches of new product. If a component of rework needs to be traced, the number of paths clearly increases, but with proper internal recordkeeping, these can be traced.

Some processed food manufacturers that IFT spoke to manufacture products for other companies. In other words, they manufacture a product and package it as another brand. It was mentioned that some co-manufacturers have an exclusive license with one company, but may sell to other companies on the side; however, we did not hear about this issue directly from processed food manufacturers. The extent to which this might occur is not known, however, this would present a major hurdle to product tracing. If there is an issue with a product or an ingredient, a co-manufacturer may not want to acknowledge that the affected product had more distribution paths than it should according to contract. Enforcement and outreach are needed to ensure that this does not occur. One firm that uses co-manufacturers requires that they use the same software and bar coding system as the brand owner, so that controls over production can be more closely monitored.

The way a processed food manufacturer assigns a "lot" is variable. In many cases, a lot was defined as 24 h worth of production. One co-manufacturer reported that their firm packs one product under several names, and assigns the product lot number according to the customer's directions.

At the case or pallet level, consumer goods companies handle multiple outgoing lot numbers simultaneously, depending on the customer (retailer or foodservice). Some include the GTIN. GTINs are unique at different levels of packaging, for example, consumer unit GTIN is different than 12-pack GTIN and 24-pack GTIN. They may also have an indication of the producing plant and production line, and time stamp that the case was packed. Code dates are not typically printed on invoices, since shipments often have multiple "lots" of product. However, this information was communicated through Advanced Shipment Notices by 1 large manufacturer, and another included lot codes on the bills of lading. Most are able to track which customers receive specific lots of product by capturing the shipment information associated with each case and pallet tag. However, one reported that due to the production and packing system, it was very possible that a case could contain product from different lots, although the time frame of production could be narrowed to the hour.

It is a common practice that packages purchased by the consumer contain bar codes. This is done to facilitate the check-out process and ensure that the appropriate price is charged for the item. The 8, 12, 13, or 14-digit bar codes applied at that level do not relate to the lot or production batch, therefore, some companies apply additional information to the consumer-level package, including a "best-by" date, a location, shift code, and line code. One firm is moving toward including 2-D bar codes on packaged products in addition to the UPC bar code. This was done in conjunction with a label change to save costs, but the 2-D bar code was deemed to provide beneficial information that warranted its inclusion in the new label. Because the shelf life of many processed foods is longer than produce, the presence of this information at the consumer level may have a greater bearing on product tracing.

More than half the participating companies have encountered recalls in their operations. The implementation of mock recalls through safety crisis or safety teams was a common practice observed in this sector.

The firms we spoke to in this sector generally had tight controls over their incoming ingredients, often specifying the type of information, and in some cases the format, that had to be conveyed. The use of electronic systems, both for the manufacture of product as well as recording outgoing shipments, was prevalent. However, there may not always be a precise correlation between the ingredients that are brought to the production floor and assumed to be used in various products. These firms also perceive a lack of interest in product tracing from their suppliers.

8.6 Food distribution

There are over 3000 food distributors in the United States (Table 8). The various categories of food distributors are broadline (carrying a wide variety of food products and a smaller variety of nonfood products); systems (serving large fast-food chains with more frequent deliveries of fewer SKUs); specialty (focusing on a product category, such as seafood or produce, or a customer segment, such as healthcare); and other (warehouse club stores, and so on).

Distributors were not identified as a group that IFT would engage for this task. However, it became evident that they play an important role in the farm-to-fork supply chain. Warehouses, DCs, and distributors that deal exclusively with produce are discussed in section "Produce." This section highlights key findings from the 3 independent distributors IFT spoke with, as well as practices in retail DCs. Receipt and handling of products seemed to be similar for all types of distributors, regardless of whether the product was fresh produce or a shelf stable food, and whether products were destined for retail or foodservice, although the technologies employed differed.

Table 8—Share of sales by distributor type (IFDA 2009).

	Broadline	Specialty	Other
Sales (in billions)	$140 (57%)	$44 (18%)	$60 (25%)
Number of distributors	1710	540	750

The general practice in DCs is that pallets are received, either directly from manufacturers or from brokers, wholesalers, or other providers. After receipt, the contents are generally checked against an invoice. Pallets are generally labeled with an internal code and tracked through the DC. It seems common for larger distributors to apply bar codes to pallets and use radio frequency to transmit information associated with the pallet and its location.

Depending on the supply, pallets may be temporarily stored before being moved to a "pick slot" which is the physical storage location for that product. In some DCs, the pick slot is pre-assigned (for example, Athena cantaloupes are always in the same pick slot). In other DCs, each pick slot has a bar code, and the lift operator moves the pallet(s) to an empty slot, scans the pallets, and scans the pick slot bar code. The latter system relies more on the operator, but those who use this system state that the number and availability of different products prevents them from assigning permanent pick slots to items.

The DC serves as a point where pallets are divided into cases. Distributors serve as consolidators, primarily for retail and foodservice establishments. An individual store may need 1 case of 1 item, 3 cases of another item, and so on. The distributor "picks" the cases required by the customer and assembles them on a new pallet.

The number of cases associated with each pallet ID is tracked. As the cases are selected for customers ("picked"), internal systems generally track the reduction in the number of available cases. The individual who is the "picker" is responsible for identifying and selecting the appropriate case. A FIFO system is generally used, so that the picker is given the pallet ID to select cases from, based on the oldest pallet ID for that product in the system. However, this can be overridden, often by the sales team working for the distributor, to provide their customers with "fresher" product.

Pickers may receive directions via a voice pick system. In this system, the individual wears a headset so that hands are free to select pallets. The use of the voice pick system seems more prevalent in retail DCs than those that service foodservice. Other distributors use a scanning device to track which pallets are selected from cases.

There are a few areas where the traceability chain can become broken in the distribution system. First, the incoming lot number (assigned by the manufacturer or previous owner) is not always recorded. Similar to other segments of the industry and other points in the supply chain, the reasons given generally related to the inability to identify which marking was the "lot number" and the inability to decipher the lot number.

Second, incoming pallets are assigned internal lot or tracking numbers, consistent with the practice observed in the produce wholesaler/distributor segment. If the pallet contains cases with different lots, this is not recorded. Therefore, when the picker receives a direction to pick cases associated with a particular pallet ID, the cases may actually have different lot numbers.

Another issue occurs when one pallet is partially depleted and a new pallet joins the partial pallet in the pick slot. There is a window when cases may be picked from either pallet, and this may not be well recorded.

One DC guessed that they spend 6 min assigning and applying a new lot number to pallets. If the pallet arrived and an existing bar code only needed to be scanned, this would save time. However, one company insisted that they would still apply their own additional internally assigned lot numbers since those link to the item numbers that are used by customers for ordering.

When very small businesses are served, a truck may be loaded with the total number of cases of a particular product, and the driver selects and delivers the appropriate number of cases to each stop along the route. Currently, some distributors are piloting programs where the driver scans the cases that are delivered to each location, but they are not specific to the lot level (instead, this is being done to prove that the correct items and quantities were delivered).

For product tracing to improve in this segment, the lot numbers associated with incoming cases must be recorded. As cases are picked, their lot numbers either need to be specified to the picker (preferable) or recorded by the picker. In order for the former scenario to be efficient, the labeling of cases and identification of the lot number must be clearly visible to the picker. Some have suggested that there be a "hook"—a bolding of the characters that distinguish one lot from another, so that different lots can be rapidly and clearly identified.

Currently, distributors shoulder enormous responsibility when a recall is issued. Foodservice establishments expect that their distributor knows what was shipped, and rely on the distributor for recall notification. At the level of the retail store, we heard that the rapid flow of product prevents them from recording information specific to deliveries, and that they also rely on their DC to record what was sent. However, based on the few discussions with representatives of this segment, it seems that they do efficiently pass recall notices (from the manufacturers) to their customers, but lack the capability of knowing which customers received specific lots of product. Targeted recalls could save distributors time and perhaps money if they knew which stores received a certain lot of product, and they would not need to contact all in the event of a recall. However, one small restaurant was provided with "targeted" information from their distributor that the type of tomato requested was not available due to a recall, but other unaffected varieties were available. The restaurant chose not to receive any tomatoes because of the outbreak, which shows that a targeted recall may not alleviate the fears of some trade partners and likely consumers, and sales of uncontaminated products may still be affected.

Although we spoke to relatively few food distributors, panel reviewers expressed that the practices described are consistent in most of this industry. Because incoming cases do not have a clearly identified (or at least standardized) lot number, this information is not typically captured. Item numbers may be applied, but are not specific to incoming lots. As distributors provide product to customers (retail or foodservice), lot numbers are not captured.

8.7 Foodservice

A comparison of practices, experiences, and requirements of restaurants and corporate foodservice operations are presented as Figure 3. Restaurants are currently exempt from the BT Act thus they rely heavily on their vendors to provide traceability information, whether they are chains or independent stores. There are currently over 450000 commercial eating establishments and over 200000 noncommercial eating establishments (for example, schools, hospitals, and so on).

8.7.1 Multi-state franchise restaurant chains. In the foodservice sector, IFT spoke to the corporate representatives of 5 large restaurant chains. Most maintain an electronic system at the corporate level for keeping records of ingredients, especially proprietary ingredients and their sources, as well as a list of approved suppliers. Most require 3rd party audits at least once a year for their suppliers. At least one reported that they recently reduced the number of suppliers of any given product, both to reduce variation in product quality as well as to improve product tracing.

More than 1 corporation has different requirements for produce compared to other ingredients. One corporation requires 14-digit product identifiers in a bar code (GTINs) on outer cases, and requires additional information on cases containing perishables, including the GLN, lot number and production date. Another is looking to begin using GTINs on all items, and currently requires a lot code but not a code date. This firm has moved toward restricting stores from purchasing local produce, and instead procures it at the corporate level, and requires lot code information. Another company required a bar code with the manufacturer, date, and expiration date. When foodservice corporations requested that suppliers add information and bar codes at the case level to facilitate product tracing, they reported little resistance.

With few exceptions, large chain restaurants seem to use independent distributors to deliver their ingredients. Many reported reliance on distributors to record which lots are delivered to store locations. For chains that require bar codes, they reported that getting the DC to capture bar code information took effort. Convincing the distributors to switch from a FIFO system (based on a distributor-applied internal number) to one where distributors scan a preexisting bar code seems to be a challenge, but one that can be met. One reported that the DC applied stickers to cases with sequential numbers, so that they felt fairly confident that they could track products by matching dates against the sequential numbers. There was an expectation that the DC records an incoming lot number, but not an outgoing one (and instead relies on FIFO and date matching). However, as explained in section "Food Distribution," distributors did not always record incoming lot numbers.

At the restaurant store level, bar codes are maintained on the box until the product is used. However, the bar codes are generally not captured or recorded. In one instance, store locations did have an electronic system for capturing bar code information, but only did so after the product was used, so that more could be procured. Inventory control is the primary purpose; product tracing is a consequence. In some cases, a sticker bearing the bar code accompanies the purchase order that provides for increased product. For many products, cases contain multiple inner packs, which are not labeled.

Another concern regarding the role of distributors was the potential for distributors to make unauthorized product substitutions if the corporation had specified approved suppliers. One company also mentioned concern regarding commingling of produce at the DC. Another limitation is the potential to reuse boxes for other products or different lots of same product.

A prevalent problem, especially from the franchise side, is the use of unapproved vendors for ingredients or fill-in suppliers to maintain inventory, particularly for fresh produce. In an attempt to limit this practice, the corporate office negotiates with the approved vendors on behalf of both franchise and corporate operations. It was also suggested that tracking delivery patterns directly to stores might serve as an alert that fill-in suppliers are being used.

Most foodservice operations had previously encountered at least 1 recall, but not all have executed mock recalls. Most companies have an efficient internal recall system in place consisting of a telephone tree or an internal portal system to notify their restaurants of a recall or other food safety issue. Most companies did not require store locations to have internet access. Franchise owners do not always have an electronic system which can curtail recordkeeping.

8.7.2 Small single stores or independent franchise restaurants. Common practices vary at small independently owned, single

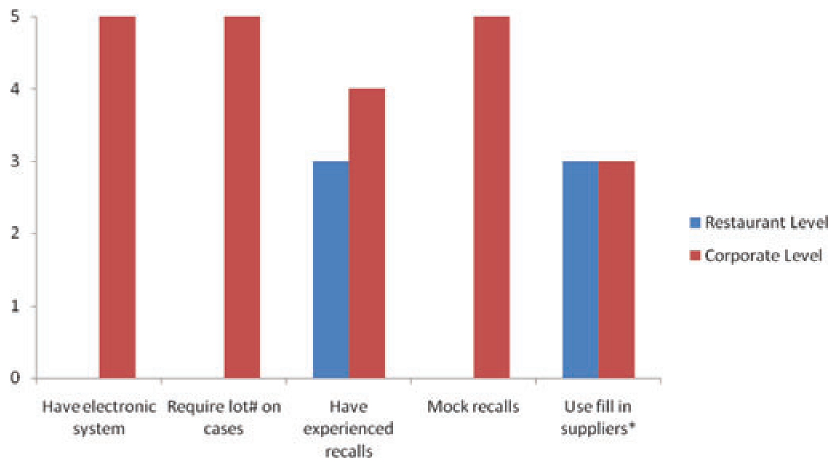

Figure 3—Comparison of restaurant and corporate level requirements, experiences, and practices. In both cases, *n* = 5. *Use of fill-in suppliers means that items are purchased at retail markets (grocery stores), warehouse club stores, and other similar businesses; for the corporate response, this indicates awareness and concern about this practice occurring in restaurants.

stores that IFT spoke to. These stores often have limited storage room so they keep a small inventory, as they do not want products to spoil, and simply do not have the revenue to cover lost product. They may use a broadline distributor for staple products, frequently purchasing split cases of product. Small, single stores are also more likely to shop at membership stores, such as Costco and Sam's Club, or local grocers to add to their own supply, which limits their 1-step back records. Participants were asked how often they procure ingredients in this way, and the responses indicated that fill-in purchasing appears to occur more than 10% of the time.

These stores are more likely to have cash transactions with customers or when purchasing fill-in product, and may not keep detailed records of these transactions.

If the ingredients and products received from distributors have lot or code numbers, they generally are not recorded. Many products do not seem to have a lot number, or they may have inner packs that do not have an identifier, even though the outer box may be labeled. Invoices may not always include item numbers, and employees often do not check products received against invoices. Staff at small single stores is limited and often busy helping customers, and they frequently employ younger, temporary workers. Small single stores also typically have limited or no infrastructure to record and manage data electronically.

Franchises rely on corporate headquarters and small, single stores rely on their distributors to provide them with food safety updates, and are not likely to keep abreast of information themselves. Very few small, single stores are members of trade associations, although one store who is a trade association member had received an update on peanut butter-containing products contaminated with *Salmonella*, showing that trade associations can be an effective avenue for news distribution to all size companies.

Although the breadth and depth of information recorded at small, single stores appears to be very limited, they do maintain receipts, often in the paper form, for accounting and tax purposes. Limited deliveries and receipts would allow them to pinpoint dates more easily, even if other documents are not maintained. Small, single stores may have the opportunity to contact customers via credit card records in the case of a major food safety recall, although this would be labor-intensive and would miss the large number of cash customers. At most foodservice operations, however, most product is turned over quickly and consumed immediately so product recalls or customer notification may occur too late to prevent illness.

Table 9—Composition of and main practices related to retail sectors.

Current practices	Percentage ($n = 7$)
Independent single operation	14%
Large retail chain corporate headquarters (> 100 stores)	43%
Medium retail chain corporate headquarters (< 100 stores)	14%
Have electronic database or system	71%
Assign internal lot number	43%
Capture lot information at store level	0%
Have experienced recalls	86%
Mock recalls in place	43%
Fill-in suppliers[a]	14%

[a]Use of fill-in suppliers means that items are purchased at other retail markets (grocery stores), warehouse club stores, or terminal markets and other similar businesses.

8.8 Retail (grocers)

Retailers, including grocery stores, club warehouses, and convenience stores, may stock thousands of different products manufactured by multiple companies, and these products are purchased directly by consumers. Our discussions focused on the traditional grocery operation, and not foodservice operations that are now common in many retail stores. Table 9 shows the main practices observed in this sector.

Compared to other grocery products, produce often has multiple suppliers, partly because of seasonality. There is also a trend toward providing consumers with "local" produce. In many cases, the farmer delivers produce directly to the store, and some stores provide the name of the farm and farmer. A few of the retailers we spoke to procure produce through a web-based system, either using a 3rd party or their own proprietary interface. These systems have the ability to record lot number, but this functionality is not currently employed.

For large retailers, products may be shipped to a company-owned warehouse before being distributed to an individual store, or stores may receive direct-to-store delivery from the manufacturer. Retailers felt that the direct-to-store delivery method provided better product tracing than delivery from a DC. Small retailers may use the services of broadline distributors.

At the retail level, most companies had an electronic system that allowed them to capture and store information. The implementation of an electronic system was observed to be related to company size or number of stores. Invoices do not typically have lot numbers, and many electronic systems are not set up to record that information, even though cases often have markings. Retailers seemed to have more control over and more information about co-manufacturers that produce private label product for the firm compared to branded products.

Most retail stores did not trace further than 1-step forward or backwards, and in many cases the trace ended at the retailer-owned DC. DCs owned by retailers may record incoming lot numbers, but this was not a requirement by all retailers. Outgoing shipments are based on the FIFO system, or if available, based on manufacturer-specified "use by" dates.

If retailers were able to better capture the specific lot numbers of products delivered to stores, the depth and precision of product tracing would be improved. However, there was still a stated concern regarding the use of "fill-in" suppliers at the individual store level. One retailer felt that his competitors purchased 10% to 15% of produce "off the street" (for example, at terminal markets, or other locations other than through the DC).

Like many foodservice locations, retail stores have limited room for inventory, have high product turnover, and have limited staff able to scan incoming product at the store dock.

From manufacturers' and retailers' perspective, there is no incentive in being able to target the affected product. One small independent co-op did check lot numbers and provided a sign to consumers that the remaining products were not included in the recall. However, a medium-size company expressed that the expense to try to read all lot numbers was more than the cost of the food item. Most expressed that removing all products reduced their liability, because they did not want to assume a potential error or misinterpretation of the lot number. Moreover, given the growing scope of recent recalls, a lot that is not originally recalled may be recalled later. Thus, they do not want to increase the risk of handling possible contaminated product. If retail stores remove the entire brand, and consumers avoid the entire product category, then brand equity is reduced over time. However, given that the removal of all product (by name for produce, or by UPC code for packaged goods) is common, there is little perceived need for trace forward capability from the DC to the store location. Once a recall notice is issued, the major retailers we spoke to all reported that they are able to block sales of the product based on the UPC code, assuming there is one.

Although most retailers have experienced at least 1 recall, only about 40% of the retailers IFT spoke to have mock recalls in place. Some commented that they do not need to practice mock recalls, since they experience actual recalls regularly.

"Customer Loyalty Cards" or other membership cards are becoming more common and have been proposed as a way to alert customers that they might have purchased recalled product. If lot numbers were associated with customer purchases, the depth of the entire product tracing system would be greater. However, few retailers have a record of lot numbers in their stores, and no retailer we spoke to tracks customer purchases to the lot level. Some have expressed concerns over privacy; however, other retailers have provided an "opt-in" notification opportunity, and retailers who do contact consumers report that this is well received by their customers. Accuracy of consumer contact information will be a challenge, as one retailer reported that 13% of customer loyalty cards were registered to "Mickey Mouse."

The trend toward procuring "locally produced" or "locally sourced" produce provides unique product tracing challenges. Since farmers are exempt from current recordkeeping requirements, and retail establishments are as well, there may be no ability to trace products.

Another important message from retailers is that in the event of a recall event, they will clear the shelf.

8.9 Summary of food industry practices

Overall, the amount of information shared and recorded between trading partners (breadth) varies, but common elements were observed to be the name of the sender and recipient, item description (which may be self-generated and not standardized) and often item number (usually internal to the sending company, and not the lot number), quantity, price, dates, and other information required by other regulatory authorities (such as the Dept. of Transportation). One of the least commonly communicated and/or recorded elements was lot number, which is critical for product tracing.

Many companies made it clear that they are only responsible for tracking one up and back in the supply chain, as required by the BT Act. This is currently the depth of product tracing information for a single company or location. The redundant silos of information that exist through one up one back tracking should be sufficient, but precision is often lacking at some point in the supply chain. Precision—the ability to pinpoint the movement of a product—is lacking in some segments of the industry and supply chain. The bar coding of cases of produce and scanning that is expected to occur at each point in the supply chain through the PTI should improve precision, since each case would be tracked. Currently, the way products are tracked through the supply chain, often by pallet, shipment, or purchase order, but seldom by lot number, make precision impossible.

The speed with which information can be retrieved and communicated varies. For companies that use paper-based systems, communication can be rapid if key information, such as a date range, is provided. In many companies, paperwork needs to be "matched up," with multiple records from the facility, such as receiving, manufacturing, and accounting (or shipping) needed to provide different pieces of information. In some companies, some of these systems may be electronic (such as accounting) whereas others may be paper-based (such as batch sheets in manufacturing). Finding a limited amount of information (for example, what was produced on a given day) can be done quickly. However, a more complicated request (for example, where was a particular ingredient used, and who received product containing that ingredient) can take substantially more time if information cannot be searched electronically.

When asked about time standards for mock recalls, companies indicated that they could gather information quickly. However, "mock recall" or "mock traceback" are terms whose definitions vary. They are currently viewed as 1-step forward/1.step back, and not through the full chain. There are a few reasons for the disparity between what companies claimed to be able to do and what is observed during actual events. Of those who conduct mock recalls, all but one limit the exercise to within their facility (for example, they do not involve their suppliers or customers). One firm indicated that when they have tried to engage suppliers, requests are ignored. We were told that companies want to verify information before officially submitting it. If they rely on their trading partners for verification, this may significantly slow down the process. In some segments, such as retail and foodservice, individual establishments do not generally keep records and need to rely on their supplier to gather information (generally a DC).

9.0 Overview of Existing and Emerging Systems

Information regarding bar codes, RFID, and the standards that govern their use are found in the section "Current Media to Aid in Traceability." This section describes some of the products that are currently used by the food industry (often for purposes other than traceability) and some of the standards that are in existence. Over the past few years, companies have emerged who offer traceability as a main component of their product portfolio. These are discussed and evaluated, and recommendations for capturing and sharing data elements necessary for product tracing systems are provided.

9.1 Electronic systems

In discussions with members of the food industry, it became evident that there are many systems and platforms that are used within a facility or between trading partners. IFT spoke to representatives from some companies that service components of the food industry, such as warehouse management system providers. The objective of these discussions was to determine whether or not systems that are already in use in companies could be modified to capture information needed to enhance product tracing. The sense is that with minor adaptations to existing software, tracing products through improved recordkeeping can be enhanced. However, substantial changes to internal practices at shipping, batching, and receiving would need to occur so that appropriate data were captured. Additionally, if information is to be shared between partners, standardization of formats still needs to occur.

Common to all segments of the food industry and all points in the supply chain was the use of WMS and accounting systems. Many of these systems were created internally, and when off-the-shelf systems were used, we seldom heard repetition of brands for most industry segments. However, it was clear that these systems serve important business functions and are heavily relied upon. Data elements needed for product tracing, such as lot numbers, were not generally recorded in these systems, or were recorded in one system but not transferred to another (for example, a WMS would track the movement of a lot, but the accounting system would not capture which invoice that lot was sent on). In some cases, companies knew that their WMS had the ability to record lot information, but that functionality was not being used.

In the produce industry, 2 types of systems were commonly mentioned. Some produce companies equated or related product tracing with an audit. There are several auditing firms that specialize in produce, and one of these provides, as an additional service, a web-based list of contact information for suppliers of a particular firm. This is particularly useful for companies that have multiple facilities.

Another system used by some members of the produce industry is based on an online platform for retailers and vendors to communicate and place orders. One company, ITrade Network, operates as a "software as a service" hosted model, and functions like an online enterprise resource planning (ERP) system. They currently have 5500 customers in retail, hospitality, and food-service industries, and $300 billion in trade goes through their system annually. Over 4000 suppliers, ranging from very large to very small, are vendors. Over 80 attributes can be captured in this system, but many, such as GTIN and lot number, are optional. Once a retailer moves forward with purchasing from a vendor, and the products are put in transit, all information regarding the order is available to the purchaser. Any variations, including substitutions, are documented through the system and provided to the customer. They have a complete transportation suite and can capture van number, trailer number, and offer GPS tracking on the truck. This system has the capacity to capture data elements necessary for product tracing, but these functions are rarely used. Instead, this system is used to facilitate business transactions.

In the processed foods industry, SAP is commonly referenced. SAP provides business management software, including ERP and supply chain management. The service can exchange data with other sources such as internet/web services, process interface and so on; and uses manufacturing dashboards to enhance access to information needed. Dashboards can be personalized to track and display information specified by the user. SAP software is configured to specific customer needs and can be modified to include information relevant to product tracing (that is, has the ability to enhance or add missing fields). SAP has the ability to provide a single integrated platform for capturing data. SAP can extract data from bar codes, RFID, and so on. Firms using SAP, seemed to use the system for in-house operations. However, using SAP platforms, information can be exchanged among trading partners along the supply chain (directly; not funneled through SAP ERP). Those who use SAP can provide collaboration portals for their suppliers. These network collaboration tools can be used to exchange information, and its use is on the rise. However, its application is generally supply chain planning (for example, communicating shipments) and not product tracing.

Electronic Data Interchange (EDI) is used to electronically communicate a number of types of transactions between trading partners. All transactions allow for the use of GTINs and GLNs, as well as other product or location identifiers. GTIN and GLN are currently not mandated, but are recommended. A 3-digit code conveys the kind of information being transferred, and each 3-digit code has a specified set of information. For example, the Inventory Inquiry/Advice (846) business message can be used by a seller, public warehouse or buyer to provide the other party with product inventory information. Inventory levels may be reported at the total product level, or they may be broken down by warehouse lot number. This information allows all the parties to synchronize product inventory. The Purchase Order (850) is used by the buyer to advise a seller or broker of a request for the delivery of product. A broker uses this to communicate the buyer's request for product to the seller. It may be an original, or it may be a confirmation of one already communicated to the seller or broker. It may also be used to express distribution requirements for receiving location(s), such as in cross-dock and/or drop-ship environments. Grocery products, by their nature, have a significantly less complicated set of product attributes that must be communicated in the ordering process. The Grocery Products Purchase Order (875) reflects that reduced complexity in the document structure and code values associated with it. The Ship Notice/Manifest (856) business message may be used by either the seller or public warehouse to advise the buyer of shipment information. In addition, it may also be used by a seller to notify a public warehouse when a shipment of product is made from the seller's plant or producing location or from another public warehouse. The Invoice (810) message is generated by the supplier to bill the buyer for products and services provided and allows a buyer to record payment-request information and automatically update applicable systems. The data contained in the business message provides automated cross-referencing of purchase order and receiving data. The Grocery Products Invoice (880) is used to request payment for goods or services within the grocery industry. The Grocery Products Invoice specifies the seller's terms of sale, delineates the products that were delivered and the quantity billed, provides item list price for each product, and documents allowances or charges that are applicable.

9.2 Globally recognized standards

One of the criteria that were important was the use of existing systems and standards. There are many systems currently available that allow for standardization—their use is simply not always standard. Thus, there may be competition between standards in some cases. Here we describe some of the ways that the different segments of the industry communicate in a standardized way. While we are not promoting or advocating for a particular system or methodology, we do feel that these tools provide opportunities to readily enhance traceability and warrant mention.

9.2.1 Identifying products. Traceback investigators have found the lack of a uniform names or descriptors of products in the produce industry. For example, a specific variety of tomato may be named according to its shape, size, color, or common name. As the same product changes hands, the name may also change, and when other data elements that provide product tracing are lacking or are not obvious, "name" may be used as a key data element.

There are currently a few systems that provide standardized recognition to produce products. One is the Price Lookup Number (PLU, a number found on produce stickers). This is a 4- or 5-digit number commonly found on small stickers applied to nonprocessed produce. This system was developed so that cashiers at retail could quickly identify an item so that the appropriate price was charged. There is an Intl. Federation for Produce Standards that considers requests for the assignment of new PLUs. Although PLUs provide some standard identification system, they are not very granular. In other words, multiple products (for example, different sizes, qualities, and so on) may have the same PLU. PLUs are also only used to identify produce at retail, not its source or if the product is being used as an ingredient or is destined for foodservice.

The Intl. Harmonized Commodity Coding and Classification System (HS) was established by the World Customs Organization. HS is an international standard for world trade at a minimum 6-digit level of detail. For example, 10 = cereals, 1005 = corn, 1005.90 = other corn, 1005.90.2020 = U.S. nr 1 yellow dent corn. There are more than 5000 6-digit codes, broken down into 99 chapters, which cover the broad spectrum of products traded globally, including agricultural products. Each country has the option of further breaking down these international HS codes into more digits and greater detail to meet their own needs, and the United States uses a 10-digit code system. The U.S. Intl. Trade Commission maintains the codes. The level of specificity of these codes for food products needs to be further examined, but may serve as a way to standardize expression of a product type.

The GTIN is a widely used system that identifies products manufactured or distributed by a company. A GTIN consists of 8, 12, 13, or 14. The (company prefixes vary in length) 7 to 12 digits are assigned by GS1 and are the "company prefix." The subsequent digits are created by the company and associated with a specific product. There are rules that govern when a new GTIN needs to be created (for example, for different product sizes, flavors, and so on). Since the 1st several digits represent the "company prefix," issues may surface in the event of acquisitions or other changes in the "brand owner." With respect to traceability, a main challenge to the GTIN system of product identification is the use of co-manufacturers. Currently, co-manufacturers are not the "brand owner"; therefore, although they are actually manufacturing the product, they are not identified in terms of the GTIN. Instead, the "brand owner" may use their company prefix and GTIN to identify the product, which creates lack of transparency regarding who manufactured the product and where this was done. Another issue that is produce specific is the use of a generic company prefix. Some produce items have a bar code that begins with the numbers "033383," which is a generic prefix. These numbers do not tie to a specific firm. This prefix is often preferred by retailers since it simplifies their systems (for example, they do not need to handle celery from every different provider separately; it can simply be inventoried and scanned as "celery"). The PTI mandates this practice be discontinued and that each brand owner receive a unique company prefix. However, a scan of a retail produce aisle shows that this practice is still widely used. As Figure 4 shows, a watermelon purchased in July, 2009 used the generic company prefix 033383 as the first 6 digits of the bar code. The number #4032 is the PLU number for watermelons. The use of this number was observed even for produce branded by major, recognized produce brands. In the observation of 2 kinds of mushrooms, both bearing the same brand, one container used the generic code while the other used a true company prefix. This can clearly create confusion with respect to product tracing. The explanation provided was that as old label stock is depleted, firms are moving toward company and product specific labels.

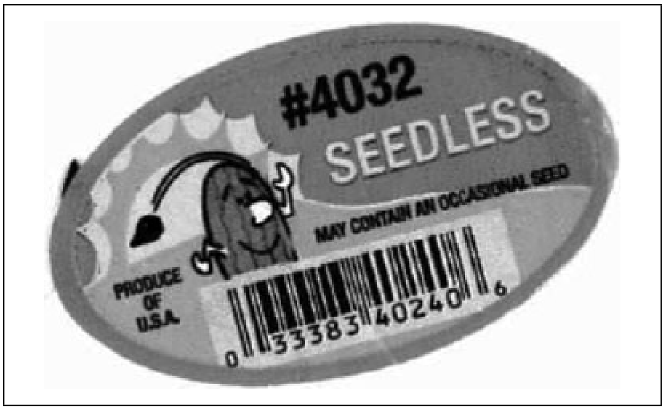

Figure 4—Label from a watermelon using the generic company prefix.

The serialized GTIN, known as the sGTIN, was originally developed for RFID applications. EPCglobal develops Electronic Product Code (EPC) standards and other tools to support the use of RFID. An EPC is a unique, serialized identifier for any kind of object, such as a GTIN. A GTIN can be encoded in an EPC by identifying an individual serialized item, while a GTIN identifies a class of items. A Serialized Global Trade Item Number (sGTIN) is the combination of a GTIN and a serial number. Two cases of the same product may have the same GTIN, but will have different sGTINs. A sGTIN consists of the following information elements:

- The company prefix, assigned by GS1 to a managing entity.
- The item reference, assigned by the managing entity to a particular object class.
- The serial number, assigned by the managing entity to an individual object.

Many industries use the UNSPSC to provide standardized naming of products. This system uses a 4-level classification including segment (such as food and beverage), then family, class, and commodity. There is an 8-digit number assigned to each element. Roughly half of users are located in the United States. USDA and U.S. Customs are researching the possible use of UNSPSC to support their Intl. Trade Data System (ITDS) product classification needs; this pilot may be starting this fall with a nonfood category. In 2007 and 2008, at the request of the USDA and U.S. Customs GS1 US worked with Produce Marketing Assn. (PMA), Canadian Produce Marketing Assn. (CPMA) and various companies to increase the UNSPSC content for fresh fruit and vegetable items. The UNSPSC content for these categories is now very comprehensive and complete. Access to UNSPSC content is available for free to interested users on the website (UNSPSC 2009) and it is often included as a classification option in ERP systems from SAP, Oracle, and so on and in procurement/supply chain applications from a number of Solution Providers. Its member/user base is global and encompasses commercial firms, governments, and trade groups.

World Food Trace is a nonprofit organization that registers 16-digit identification numbers that a firm can assign to a lot or other unit of product. Licensed data service companies host the data online and providers must follow standards set up by the nonprofit arm. Large companies may host their own database.

This approach is modeled after the way companies register domain names on the Internet and then hosting companies provide "DNS" or domain name servers that "serve up" data to other DNS servers on the internet about the customers who registered through them.The first 2 digits in the ID indicate region/country of origin (based on United Nations list of regions and countries). The ID includes a date/time stamp so that companies will have to maintain accurate internal records so they can determine what product was running on a line at that time. It is up to each plant to know which ingredients went into that product, perhaps using a different system for internal traceability. Advocates of this system note that less company-proprietary information is shared in this system.

9.2.2 Location identification. There are a few systems that identify locations in a standardized fashion.

The GS1 System includes GLNs. One current obstacle to using GLNs is that it is assigned to a company, and the company then assigns individual numbers to each facility (for example, plant). However, this information is not available in a master database, so even though each plant may have a unique GLN, the facility location would not be readily available to regulatory agencies. An advantage to using the GLN system is that it is used in 23 industries in the United States. Since many companies in the food supply chain deal with products other than food, the use of GLNs is advantageous since this reduces the need for a single facility to manage multiple forms of location identification. For example, GLNs are used in the pharmaceutical industry, and some food ingredient suppliers also serve the pharmaceutical industry. At the other end of the supply chain, retailers commonly use GLNs. If GLNs are selected as a means by which industries convey their location, we recommend a registry similar to the GLN healthcare registry, which is a database of GLNs, be created.

In accordance with the BT Act, food processors are required to register with the FDA. FDA assigns a registration number to each facility, and in theory this could be used as a standard identifier. However, this is a U.S.-based system, and may not be applicable on a global scale. Also some segments of the food supply chain are currently exempt from registration. Currently, there is no requirement for companies to update this database, and there is concern that information may not be current. There was also a sense that facility registration numbers are not to be communicated due to concerns about disclosing the locations of facilities.

Approximately 10000 produce companies are listed on the Blue Book Online Services (BBOS). Blue Book Services provides in-depth business and credit information on companies in the produce industry. It is a comprehensive database with a search engine that provides real-time information on produce sellers, buyers, transportation, and supply firms that are located in the United States, Canada, Mexico, and other international locations. Produce companies can use this information to find new vendors, customers, transportation, or supply firms to do business with. There is no charge to list basic company information in the Blue Book so many companies take advantage of this service and become "registered users." Basic company information includes name, address, phone and fax number, e-mail address, website, as well as certain licenses, classification, and commodity information. Additional information can be added to a listing for a charge. Registered users are assigned a 6-digit Blue Book number. Registered users are companies that are not Blue Book Members but have an e-mail address and a password for limited access to BBOS. A registered user can perform limited company searches, purchase Marketing Lists and Business Reports and view all company contact information. A Blue Book Member is a company that has purchased a level of membership to have greater access to the services offered by BBOS. It is up to companies to update their listing if changes occur, but requests for updates are frequently sent. In the mock tomato traceback conducted as part of TO7, the Blue Book number was one data element used to identify produce companies.

States often have their own systems for identifying locations. For example, dairy processors are currently assigned a facility number by the state as part of the Pasteurized Milk Ordinance. Roughly 20 y ago, states transitioned from using their own numbering system to identify dairy processors to adopting a more structured system. Currently, each state is assigned a 2-digit number based on its alphabetical order (for example, Alabama = 01). Dairy processing plants are designated with the 2-digit state prefix, followed by additional numbers or letters, depending on and assigned by the state. Typically, the 2-digit prefix is followed by 2 or 3 numbers. The plant codes for facilities producing fluid milk, cream, yogurt, cottage cheese, and buttermilk are maintained by and freely available from FDA. Every 2 y, state employees evaluate these plants to ensure they qualify to remain on the list, and the list is continually updated. Facilities producing cheese, butter, nonfat dry milk, and whey powder are identified using the same numbering system. This list is maintained by USDA; however, although each facility must have a state-designated number, there is no requirement that they be listed on the USDA list. It is estimated that roughly 75% of these plants are on the USDA list, which is also freely available (Sayler 2009). To identify the remaining 25% of the cheese, butter, nonfat dry milk, and whey powder by plant code, one would have to call the state indicated by the first 2 digits. Although the same identification system is used for frozen desserts such as ice cream, this list is not maintained by a government agency. Intl. Dairy Foods Assn. (IDFA) works with states to maintain the list and is confident that it is comprehensive. The list can be purchased for a small fee, but IDFA does provide information to regulators free of cost.

9.2.3 Expression of time. As noted previously, different parts of the world express dates and times using different formats. However, there is an ISO standard, 8601, that specifies the format for date and time (Intl. Organization for Standardization, 8601). Simply put, the numbers go from largest to smallest, beginning with year, month, day, hour, minute, and second.

9.3 Solution systems

There are a myriad of companies offering solutions for traceability, most of which have emerged within the past decade. Some liken the current environment to the "dot com" era. IFT spent from 45 min to 2 h speaking to representatives of a relatively small number (13) of these companies to gain some understanding into the nature of their systems, cost of usage, and current adoption rate, if any. After reviewing the data collected through these conversations and demonstrations, the subpanel felt that the companies provided a representative sample and that although many other providers exist, there would be little benefit in a more comprehensive search of these types of companies. These companies were also assured anonymity and given the opportunity to be listed as participants (Appendix G).

Solution system providers use a variety of approaches and media to achieve partial or full traceability. Most reported interoperability between systems (for example, different parts of the supply chain using different systems from different vendors). However, when probed further, it seems that this is still a challenge, even if the information is standardized. There were commonalities among many companies: most are relatively new (5 to 10 y old); many got their start in providing product tracing either for the pharmaceutical industry or animal industry (as part of Animal ID); most are headed or staffed by computer scientists (as opposed to those with detailed knowledge of food systems); and most offered traceability as an added benefit to the core purpose of their system.

We found that "solution providers" could be divided into 3 main categories based on their approach to product tracing as follows:

- Product tracing as a component of temperature monitoring. These companies whose main business is temperature monitoring now provide product tracing as an "add on."
- Product tracing as a separate medium. These are companies who manufacture and track a unique medium, such as bar codes, for customers.
- Product tracing by providing a platform for information transfer. These companies provide software to link existing data between different members of the supply chain.

Each type of approach is discussed in more detail below, with specific advantages and challenges identified.

9.3.1 Evaluation criteria for solution systems. In evaluating the myriad of systems and technologies commercially available, a set of guiding principles was established. Effective systems were those deemed to:

- Leverage existing transactions in the supply chain
- Use distributed rather than centralized databases
- Develop or utilize a common standard that allows querying of data
- Leverage existing network technologies for example XML to develop software

Component of temperature monitoring. Perishable products may be shipped with temperature monitors. These come in a variety of types, from color indicators, and monitors that are returned to a central location for data upload, to monitors that the recipient can download information from (such as those that use RFID).

There are a few companies who specialize in temperature monitoring ("cold chain management") who have created an option to enter additional information *on* RFID-based monitors, or *associate* a monitor ID with additional information using web-based software.

Additionally, some have developed thermally activated inks that can be used to develop bar codes that, when activated, interfere with the standard bar code on a product and are recognized by a scanner as product that has been held out of spec. However, this ink is still used as a bar code, and unless the bar code is unique for each individual product, the cold chain feature offers no explicit product tracing function.

Analysis:
Advantages:

- If these temperature monitors are currently in wide use, tracking the movement of a tag would result in an improvement in traceability.

Challenges:

- The sense from some in the produce industry is that these tags are not always used (for example, when different products must be shipped together, and the temperature ranges do not overlap, temperature monitors are not used since they will show temperature violations).
- Temperature monitors are costly and therefore, are never used on every item. At best they are used on a case, but more frequently limited to a pallet, and often only 1 or 2 monitors on a truck are used. This severely limits the usefulness of the monitor for traceability purposes.

  a. It is common for multiple types of products, from multiple sources (for example, multiple farms) to be shipped together on 1 truck. If there are only 1 to 2 temperature monitors on a truck, product tracing cannot be accomplished.

- Product tracing is lost when items are unpacked, such as on a grocery store shelf, or likely, even earlier in the supply chain.
- Infrastructure is needed regardless of whether the monitor contains tracing data (scanners/readers are necessary) or if the unique ID of the monitor provides product tracing (this number will need to be recorded, and ease of product tracing depends on storing the number in a centralized location, similar to bar codes).

Tracking of a unique medium. Some companies offer traceability by providing both a unique medium, such as a printed bar code or RFID tag, as well as a software system to track the movement of those media as they move through the supply chain.

Analysis:
Advantages:

- This was the only type of system whereby each individual food product could, in theory, be tracked from the farm to the table, or rather, from the table to the farm, without capturing intermediate handlers, which would need to be identified for product tracing.

Challenges:

- Adhesion of the label (such as a bar code) to every product.
- Space required (as a percent of the total package or item size) for a label or tag.
- Labor required to read each number, and data synchronization challenges between trading partners.
- There is a need for all supply chain partners to track this information, or product tracing is lost.

Information transfer platform (software as a service). The majority of vendors do not provide RFID tags or bar codes; instead they simply gather information in a centralized location (on a computer server) or through a distributed network and "connect the dots" between suppliers.

The mechanism for this "software as a service" (SaaS) varies: in most cases, the provider pulls information on manufacture dates, locations, lot numbers, recipients, and so on from each point along the supply chain. In limited cases, the solution provider offers services beyond traceability (such as inventory management) and uses the information to provide traceability.

Analysis:
Advantages:

- If data exist in different systems, these solutions provide means for relating those data in a way that can be quickly queried.
- If data exist in paper form (such as paper bills of lading) they can be scanned and electronically associated with the record for the components of the shipment.
- Most SaaS systems can accommodate information from a variety of sources, including bar code scans, RFID scans, or manual entry
- They can also usually interface with existing systems in a company (such as an inventory system) to automatically capture information, limiting the amount of labor required for use. However, this ability is highly dependent on the specifications of the system, and the data format issues are addressed below.

Challenges:

- When SaaS providers mention flexibility in their systems, this is interpreted as the need for the client (food industry) to have IT support to build the necessary applications or make modifications so that the solution fits the needs and requirements of the client. Some members of the food industry lack IT support, and therefore, the internal resources to make these modifications.

- This type of system requires that there actually be linkages between points in the food supply chain. For example, if a plant receives ingredients that do not have a lot number, or the lot number is not recorded, this type of system is not functional. Similarly, if the incoming ingredient lot numbers are recorded, but they are not related to use in a specific batch of finished product, the appropriate links cannot be made.
- The format and standardization of data need to be agreed upon by all contributing partners in a supply chain.
- All in a supply chain need to use the same SaaS solution. In some cases, all are required to pay for the service; in other cases, there are ways that data can be uploaded (but not retrieved without payment), but all who are in contact with the product still need to transfer data to the system.

9.3.2 Summary of technologies and systems. In general, our findings showed that existing product tracing companies are developing proprietary solutions that do not have universal appeal. If the question is whether or not the technology exists to enable a specific product, such as a tomato, to be tracked from the field to the consumer table, the answer is yes. This could be done by applying a bar code or other unique identifier to the tomato (assuming it adhered and did not wash or rub off, and assuming that handling resulted in a "readable" scan at the point of purchase). However, this would require communication and cooperation at each point in the supply chain, which is currently not readily accomplished. It is worthwhile to note that the vast majority of these companies do not market themselves as providing product tracing solutions, or at least not as providing product tracing exclusively. The products are marketed in different ways such as:

- Inventory control, with the goal to reduce "shrink" and improve profits was often cited as a reason for the food industry to use a particular system.
- Cold chain management, with traceability as an added bonus.
- Marketing tool for the food industry, to show their customers (consumers, especially) where products came from, to increase brand loyalty.
- Compliance with "big chain" retail requirements.
- Food quality management.

The issues faced include:

- Cost.
- IFT asked each solution provider for an estimate of the cost of their service; no service was free. In many cases, the cost was related to the size of the subscribing company. The costs varied widely and were expressed in a variety of different ways, making them difficult to compare. The service fee for software as a service, a commonly offered product tracing solution, tended to range from $6000 to $25000 per year, depending on company size, and is further discussed in Volume 2 of this report (Institute of Food Technologists 2009).
- Food industry infrastructure.
  - Some of these approaches require that the food industry have uniform ways of expressing and storing information.
- Many of the "solutions," particularly the SaaS solutions, have the technological capability of tracking each individual food item. However, most of those that have found commercial application are currently limited to case level (at best), because the food industry has not provided unique identifiers to each individual package/box/banana and so on.
- Need for additional labor and expertise such as information technology specialists.

An additional concern is the fact that "solution providers" are new companies. There is a concern that these companies may not be sustainable. Food companies using these services (either by investing in hardware or software), especially if core business operations (inventory and so on) are hosted on the "solution provider" server, will suffer setbacks if the "solution provider" goes out of business.

With respect to the claim that improved product tracing will benefit companies because the scope of their recall would be limited, we found that this was of very little consequence to food companies. One firm stated that brands defend their assets and will always recall more than just the affected lot. Thus, it was stated that narrowing the size of a recall is really an "academic exercise." At the retail level, there was concern over the liability of having a recalled product remain on the store shelf, so the commonly reported practice was that the product would be cleared from the shelf, without regard to a specific lot number. Additionally, some commented that many firms do not believe they will ever need to conduct a recall, so that the benefit of narrowing the scope of a recall would not be perceived to apply to them.

9.3.3 Recommendations for systems and technologies. There was a general agreement that many information technology companies have expertise required to build solutions once standards are available (for example, IBM, Google, Yahoo!, SAP, Oracle, Microsoft, and many smaller players).

The panel believes that being able to reach specified objectives (such as those proposed in section "Objectives") would represent a measurable improvement in product tracing, greatly enhancing the protection of public health. There is a sense that for the industry to collectively meet the objective of an accurate and rapid traceback, an electronic system should be used. To provide flexibility for cost-effectiveness and technology capability, a subpanel, who explored how an electronic system could function, provided the following recommendations for its infrastructure:

- Data elements specified in Table 11 that need to be communicated to a regulatory authority could be transferred to searchable databases by any effective means or medium available: pen and paper, bar code, RFID, or others. All companies would have to collect and store a minimum set of data standards that would be associated with the case. (The required data elements, such as those proposed in Table 10 should be specified by FDA.)
- In the event of an outbreak investigation or food-related emergency, ownership of data would remain with the contributing company. Upon request by FDA, companies would need to provide data in an electronic format within 24 h. There are 2 main ways that data could be transmitted to FDA in an electronic form. Companies could either "push" data, or allow FDA to "pull" data. Further investigation into the pros and cons of these scenarios is needed to determine the most suitable approach for FDA and industry. In either case, FDA would ultimately have the means to query data sets. Software, such as that being piloted through IFT Task Order 7, would be developed to enable querying and analysis of production and distribution data that had been requested.
  a. IFT expects that modifications or upgrades could be made to existing electronic systems (for example, WMS), using existing network technologies to ensure that electronic records were available.
  b. Third parties could provide a web interface for small businesses to maintain product tracing data, if a

Table 10 — Recommended data elements.[a]

	Required	Suggested
Provided to a regulatory authority upon request	External critical tracking event (one forward/backward) Quantity shipped/received Shipment/ receipt date Lot number Ship-to/from location Internal critical tracking event Production date Ingredient/input lot numbers Finished lot number Quantity	One forward/backward: Pallet identifier
Invoice	Lot number(s) Quantity (for example, nr cases)—shipper name, address, contact info Recipient name, address, contact info Date of shipment	Pallet identifier Product code Item code
Pallet	Pallet contents (for example, if the pallet consists of different items or lots, the pallet identifier must reflect this)	
Case	Lot number Location of production (inc manufacturing line) Date of production Product name Unit size Quantity (number of units) Product code	Time of production Product code
Consumer package[b]	Lot number Product name Brand owner name and phone number	Time of manufacture Manufacturing line Name of manufacturer Full contact information of brand owner If UPC is included, the company prefix should be brand specific, not generic

[a]As suggested in the table, the key data elements must be able to provide links between Critical Tracking Events so that products can be followed through the supply chain.
[b]Some products, such as low-acid canned foods and infant formula, are required to have specific information permanently visible to the naked eye: The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed (21CFR 113.60(c)).

company lacks the means to manage their data in an electronic format.

- For operations where only pen and paper are used, daily logs could be faxed or otherwise transmitted to a 3rd party, who would transcribe and house the data in a database, or a similar system able to convert written or printed text to its electronic form. This would allow easy data retrieval and facilitate a firm's ability to provide electronic records to FDA within 24 h.
- Data would not be publicly available and security of data needs to be ensured. FDA currently has the authority to access records in limited circumstances as specified by the BT Act. In the recommendations presented here, access is obtained through electronic means which is expected to facilitate traceback investigations.
- Each member of the supply chain should contact their suppliers to provide information or access to information by FDA. This access may also be activated at the request of a regulatory authority. Consideration of the use of this information by regulators other than FDA (for example, state and local investigators) needs to be further examined.

9.4 Electronic records as defensible, verifiable records

FDA requires most food companies to maintain 1 step up and back records for up to 2 y, depending on the shelf life of the food, currently under the BT Act. The Act allows companies to maintain records in either paper or electronic form as long as they are available for inspection. Also, copies need to be available for FDA within 24 h of an official request. The question of admissibility of electronic records in judicial proceedings came up during discussions of the Expert Panel. With the exception of proprietary documents that FDA may not review at any time (such as recipes, research, and pricing data), records that will "hold up in a court of law" are a matter of the Federal Rules of Evidence.

The Investigations Operations Manual provides extensive discussion of how FDA inspectors must handle documents, whether in hard copy or electronic format, so that should there be an enforcement action at a later date, the inspector will be able to authenticate the document in litigation. The FDA inspector who obtained the documentation must "be able to testify where, when and from whom the copies [of a record] were obtained, and that the copy is a true copy of the source document, based on their review of the source document"to use the document in a court action case against a company according to the FDA Investigations Operations Manual, Section 5.3.8 (FDA 2006).

The Investigations Operations Manual identifies in various Sections (5.3.6.2, 5.3.7, 5.3.8) types of documents and records that FDA may seek and use in court enforcement action/litigation, including:

- Organizational charts, company publications, letters, memos, and instructions to employees to document responsible individuals.

- Good Manufacturing Practice records.
- Commitments made in the drug Pre-Approval process.
- Adherence to the requirements of the Low-Acid Canned Food regulations.
- Records to document interstate commerce.
- Product labeling and promotion.
- Documents that identify the party or parties responsible for a variety of actions.
- Guarantees and labeling agreements.

Whether a particular document is admissible will depend on other factors, including whether it may be authenticated as to source. There are separate procedures under the Federal Rules of Civil Procedure and Federal Rules of Evidence which apply should FDA seek documents in litigation from a party. Other rules of evidence still apply, for example, hearsay rule, relevance, admissions against interest, and others so that even if an FDA inspector is able to establish authenticity, the document still must be otherwise admissible.

Other federal agencies allow the use of electronic documents for reporting purposes, and are able to use the actual electronic documents or information from them in enforcement proceedings. For example, the EPA allows electronic reporting under the Cross-Media Electronic Reporting Rule (CROMERR), which went into effect on January 11, 2006. CROMERR established electronic reporting as an acceptable regulatory alternative to paper reporting and established requirements to assure that electronic documents are as legally dependable as their paper counterparts. The requirements specify that documents, which do not include faxes, must be submitted to the Central Data Exchange (CDX) or another e-reporting system designated by the administrator (and that systems must meet CROMERR standards), and states that e-documents must have valid e-signatures, if a signature is required on the paper document. EPA must give notice of any CDX hardware/software changes that may affect report transmission and EPA can decide to grant approval to EPA-authorized programs that submit an official request for approval from to begin receiving e-reporting, if they were not included in the original rule. Nothing in CROMERR limits the use of e-documents or information derived from e.documents in enforcement proceedings covered.

Electronic records should be viewed as equivalent to paper records, and EPA has already moved forward with accepting electronic records. In many instances, when IFT asked firms what information they provide to regulators, they indicated that they print hard copies of files that exist electronically. Providing data in an electronic form enables rapid data analysis that will ultimately protect public health without jeopardizing the legal aspects of an investigation.

10.0 Recommendations

An effective product tracing system results in the protection of public health. In the short term, public health is protected by tracing a contaminated product forward so it is not consumed, and in the long term, by identifying and addressing the root cause of an outbreak, so that controls can be put in place to prevent a similar event from occurring in the future. An effective product tracing system also provides more rapid resolution to a food safety event, so that public confidence in the food supply is maintained, and disruption of commerce is limited. The panel felt that setting clear objectives, and allowing the industry to determine how to reach those objectives, was the most appropriate approach. Ways in which the objectives could be met are provided, and the use of globally recognized standards is advocated.

10.1 Guiding criteria

1. Simple
   a. Reduce opportunity for error
2. Globally accepted
   a. Standardized, while allowing for innovation
   b. Suitable for a global food supply; isn't U.S.-centric
3. Leverages existing systems
   a. Helps control cost
   b. Increases likelihood of adoption

10.2 Objectives

1. To help FDA rapidly and accurately trace a food product or ingredient through the supply chain to the originating source, as well as trace from the source forward through all distribution points to the point of sale or service.
   a. Accuracy is affected by the form in which information is transferred. Handwriting information limits the ability to rapidly trace product and may also adversely impact the accuracy of information through introduction of transcription errors.
   b. Standardized data elements are essential. Nonstandardized data elements can slow the linking of traceback information between companies and regulatory agencies, even when these records are available in an electronic format.
2. To enable communication of key data elements for critical tracking events (CTEs) that link product shipped between trading partners as well track product movement and transformation within a facility. Key data elements should be specific to the lot level, and provided to a regulatory authority, upon request, in an electronic form and within 24 h, and maintained for 2 y or for the shelf life of the product, whichever is longer. Key data elements for CTEs that provide external tracing include:
   a. Who: name of the firm sending/receiving the product.
   b. What: unique, lot specific, product identifier (discussed in detail below).
   c. When: date and time the product was received and/or shipped.
   d. Where: physical location of product origination (including processing line) or destination.
   e. How much: quantity (in cases, pounds, and so on).
3. To achieve recording of original, vendor-supplied lot numbers of ingredients and association with the lot number of the finished product (internal tracing), regardless of whether or not an "internal lot number" is assigned.
4. To ensure that key data elements are accurately recorded so that links between every critical tracking event (both external and internal) exist. This enables ingredients and products to be traced from the point of origin to the point of sale or service.

10.3 Summary of recommendations

It is necessary that firms maintain records that show 1-step forward and back product tracing (to the point of origin, if appropriate), as well as information that links products within a facility (such that the relationships between incoming and outgoing products are specific to the lot level). These records should be maintained for 2 y (or the shelf life of the product if greater) and the information should be provided in an electronic format within 24 h of an FDA request. While the panel did not feel that an electronic system would be required at the firm level, it is recognized that achieving this objective would be greatly facilitated through the use of an electronic system. Feedback from state traceback investigators indicated that current noncompliance with the BT Act requirements is caused in part by the prevalence of paper-based systems.

Additionally, there are specific points in the farm to food continuum that should be identified as CTEs. CTEs are those points such as receiving, shipping, and product transformation (mixing, repacking, and so on), during which key data elements need to be recorded for the purposes of product tracing. The information recorded at CTEs provides the links within the product supply chain. Neglecting to capture appropriate data elements at a CTE will result in a break in the product tracing chain, since information changes, such as changes in lot numbers, are captured at CTEs.

To improve the breadth and precision of information needed during product traces, and enhance accessibility of this information, each supply chain partner must:

- Identify CTEs to trace products
- Record standardized key data elements for each critical tracking event that link incoming with outgoing product, whether product is transformed (internal tracing) or changes location (external tracing).
- Provide FDA key data elements in an electronic form for each critical tracking event within 24 h of a request.

Standardized ways of expressing key data elements should be agreed upon.

Education around CTEs and key data elements should be developed, and evidence of appropriate implementation should be part of standard audits.

10.3.1 Justification. The 1st objective sets the stage for all other objectives: tracing a product or ingredient forwards and backwards needs to be done rapidly and accurately, which will require effective internal and external product tracing.

The panel deliberated the type(s) of information that must be communicated between trading partners. Two options were proposed. In one scenario, each firm would maintain the information related to key data elements in Table 10, but would simply communicate a transactional identifier to trading partners. The transactional ID could be at any level or granularity. For example, each case could have its own transactional ID, which would link to the details about the product. An advantage to this system is that a single string of characters would be used to create the links in the traceability chain, which should facilitate a trace. Each party would still be responsible for maintaining key data elements, but would not share them with trading partners or others outside of a regulatory request. This system, described in more detail in Appendix I, relies upon trading partners maintaining internal records. This concept was only explored at the tail end of this task, and warrants further study. There is concern that, in this system, there may be instances where the incorrect information is being recorded and associated with the transactional ID, and that this would not be evident until the data were requested due to a triggering event. There was also concern that this approach does not aid in moving toward standardization.

The sense of the panel was that key data elements *should* be communicated between trading partners. The panel believes that the uniqueness and distinction of products should occur at the lot level, with identification of that lot on each case of product. The responsibility should begin with the 1st party that closes the 1st case (for example, ingredient) and end with the party that opens the case before product is made available to consumers (for example, restaurants, grocers, and so on). Accurate recording and transmission of lot numbers, as well as additional information detailed below, by all members of a supply chain, will enhance the ability to trace products.

In large multi-location outbreaks, the quantity of food affected is larger than 1 consumer distribution unit (for example, a batch of product is contaminated, not just 1 package; a day's harvest is suspect, not just 1 tomato, and so on). Therefore, as indicated below, the panel believes that each *lot* of product should have an individual identifier, not each product in a case. The definition of "lot" is considered to involve transformation of one or more products (for example, ingredients becoming a finished product; tomatoes from different lots being repacked to a single case), and should not be confused with the concept of applying a new number such as an item number to a product or ingredient that will *not* be transformed.

Input from those involved in traceback investigations indicated that the 1st point in the traceback (for example, the restaurant or retail store) is generally known through the epidemiological investigation. Even for packaged products, the packaging material may be gone, so identification at the level of the individual package would not aid a traceback investigation. To trace forward and protect public health, it would be advantageous to know which consumers purchased a particular contaminated product. In this instance, the presence of lot information on the consumer unit would be useful. The issues surrounding tracking this, including the extent to which this is currently being done (for example, via retail "customer loyalty cards"), is addressed in section "Retail."

The 2nd objective specifies that the amount of time in which key data elements for CTEs must be provided to FDA is 24 h. The panel found that most companies believe they are already in compliance with the time specified above for providing 1-step forward, 1-step back information. However, because of the nature of their systems and often manual processes involved in retrieving and linking information, even within one facility, they often fall short. Also, a standardized format for data elements submitted to FDA will help companies ensure they are recording useful data that provide internal and external product tracing. State traceback investigators agreed that standardization would help them reconstruct the path that a product followed.

Table 10 shows the information that the panel believes must be shared between trading partners and communicated to a regulatory authority for effective product tracing. It also includes information that should or could be included to further enhance product tracing. The key data elements on the list, or the terminology used to describe them, may vary by industry.

For the system to function as intended, the following must be taken into consideration:

- Farms that hold commercial contracts should not be exempt from providing information regarding harvest date, lot number, and other key data elements to trading partners or regulatory authorities.
- Although brokers may not possess a product, they should be responsible for conveying key data elements between the supplier and the buyer, and must maintain records of these transactions.
- Exemptions based on business size should not exist. Without participation from every party in the supply chain, the links will be broken. It is recognized that smaller businesses may not be involved with or aware of trade associations and their initiatives, and that communication with and education of small businesses continues to be a challenge. Outreach to these groups must be developed.
- The same information needs to be captured and communicated regardless of whether the product will be used as an ingredient or is the finished product.
- Information printed on a case or pallet must accurately correspond to all of its contents.

- Standardized forms to communicate information, such as date (for example, based on the ISO standard), location (for example, latitude and longitude), product classification (for example, PLU, UNSPSC), and so on must be agreed upon.
- Information must be captured whenever the case or pallet is moved to another location, even if ownership is not transferred (for example, when a pallet is moved from one DC to another). Similarly, there must not be exemptions for vertically integrated operations (for example, the data elements transferred for a "branded" product compared with a private label should be the same).

We realize that that 1-step forward or back may cross international borders, and the expectation that a firm should be able to trace across international borders exceeds the jurisdiction of the US FDA. However, today's global nature of the food supply warrants this recommendation. The panel believes that if a company finds it advantageous to purchase product from another part of the world, there should be a responsibility associated with such procurement actions in today's global food supply.

The panel considered recommending that responsible parties be able to trace the *full* supply chain back within 24 h (that is, more than 1 step). However, tracing only 1 step is currently a significant challenge for many companies. Thus, the panel anticipates it would be impossible to expect companies to do more at the current time; this perspective is supported by feedback from the industry subgroup. Therefore, the panel recommends increased education of all members of the food industry around the core principles of product tracing, so that current regulatory compliance can be attained. State traceback investigators in various parts of the United States agreed that compliance is lacking, and that having accurate information within 24 h would enhance their ability to conduct investigations. Additionally, the accuracy of information could become compromised if full information on all steps back was required within 24 h. Feedback from the industry subpanel stressed that they want to be certain that information they provide during an investigation is accurate and complete, and that 24 h provides adequate time to cross reference and verify information. Requiring information on more than 1 step forward and backward in 24 h would decrease their confidence in the accuracy of information. This could subsequently compromise and complicate an investigation instead of expediting it.

With respect to the oft-heard concern that "middlemen" such as brokers or distributors do not want to share their supplier or customer lists for proprietary reasons, the panel believes that this argument is inadequate for several reasons. First, the liability mentioned previously should supersede the purported privacy issue. Second, since most cases of food products are labeled with the initial manufacturer or farm, the buyer already knows the source of the product, but chooses to use brokers, distributors, and so on because of the convenience and other valuable services they provide in consolidation of supplies. The panel does not believe that businesses will lose suppliers or customers by requiring that key data elements be communicated between trading partners. However, the protection of proprietary information does need to be assured, so specificity is encouraged when a regulatory agency requests information.

10.3.2 Defining a "lot" of product. The definition of a production lot should be determined. Each firm should determine the size or quantity of a particular lot. However, a lot should consist of a definite quantity produced under uniform conditions (ICMSF 2002), and should be as small as possible and generally not exceed 24 h of production. For low-acid canned foods, "the packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of four to five hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift" (21CFR 113.60(c)). We recognize that the size of a lot has implications for product sampling, and that limiting the size of lots produced under continuous processes may be difficult. The size of a lot represents the economic risk a business is willing to accept if the product is subject to recall. Assigning a new lot number to a finished product each time the lot number of an ingredient changed is considered a best practice.

The definition of "lot" is used here to indicate a combination, transformation, or manipulation of one or more products or inputs, and should not be confused with the concept of applying a new number to a product or ingredient (for example, internal tracking or item number) that will *not* be transformed. In the context of a repacked product, such as tomatoes, it is appropriate to define a "lot" as the repacked case that consists of individual tomatoes from multiple lots. In the case of a processed food, multiple ingredients are combined to make a "lot" of finished product.

The way in which a production lot is identified and labeled should be based on compatible, globally accepted, recognized standards. Each lot of product should be identified at the case level with a lot identifier. Individually packaged products may still be uniquely coded as well, if that is customary for that industry segment or company. The medium used to convey lot information, production date, and location of manufacture is relatively unimportant and independent of the system used (for example, bar code, RFIDs, electronic, or pen-and-paper could be used). These data elements should be applied by the manufacturer ("the last one to close the box").

10.3.3 Standardization of key data elements. The key data elements that need to be identified should be expressed in accordance with an agreed upon, globally recognized set of standards that are compatible. The use of globally recognized standards will increase interoperability.

As discussed in section "Globally Recognized Standards," there are currently several location identifiers in existence, for example, the GS1 Global Location Number (GLN), FDA facility registration number, latitude, and longitude (as illustrated in Table 11), state ID, plant ID, and others. The numbering system chosen should have a database that can be accessed by FDA (for example, latitude and longitude are publicly available; if state ID is chosen, FDA and perhaps other states need to be able to link that ID with the details about the facility). It may be advantageous for all facilities, from farms to retail outlets, to use the same location identification system. However, it is feasible that the system could be constructed to accommodate a limited number of location formats, such as those mentioned previously.

Although we recognize that each firm has a different schema to identify lots, it would be ideal if the way a production lot is identified forward and backward through the supply chain could become standardized. Each lot of product would be identified uniquely, with standardized elements (for example, product, plant ID, date, quantity, lot code, and so on). The specific kinds of identifiers and the types of records they are relayed upon (for example, bill of lading, delivery ticket, invoice, and so on) should be determined by the industry segment or company, as long as the objective (24 h to provide 1-step up and back, as well as internal links) is achieved. Table 10 presents the panel's recommendations on the types of information that should accompany the product, case, and paperwork. Each handler of a product or ingredient should record the key data elements for each CTE in their facility.

Table 11 – Example of how location and lot can be expressed.

Field description	Unique identifier component	Value
Peanut Corp. of America	Location of plant in latitude and longitude	N31.383020W84.918866
1.1.2009 12:24 PM	Time of production for lot	090011224
Line 2 ***this field optional***	Production line	002
Combined elements to create unique ID (printed on case or finished product)	N31.383020W84.918866090011224002	

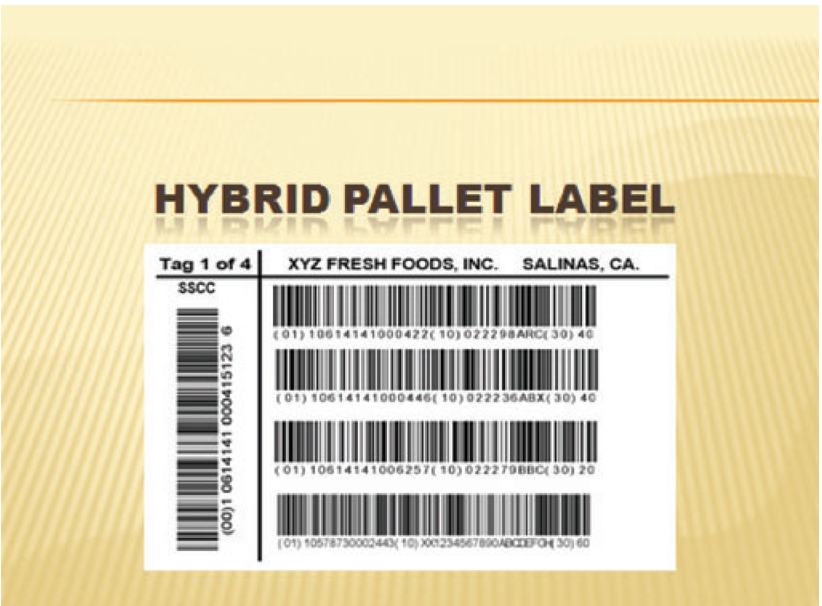

Figure 5 – Example of a hybrid pallet label that communicates how many cases of each lot are present on a pallet, developed as part of the PTI (Produce Traceability Initiative).

10.3.4 Critical tracking events (CTEs). CTEs are points where data capture is necessary to maintain product tracing. CTEs may be internal or external to the organization. Examples of external CTEs include receiving and shipping. Examples of internal CTEs include batching, aggregating, mixing with other ingredients, transformations, and so on.

Incoming lot numbers are one of the key data elements that need to be captured and made available to FDA in an electronic form within 24 h of an official request, and the point of receiving will likely be the 1st CTE identified in each facility. From a practical standpoint, recording each lot number off each case may require additional labor and slow operations. Since this information should also be printed on paperwork that accompanies or is related to the product, examining lot numbers in a pallet should be done as verification. Mechanisms exist whereby a pallet label can readily communicate the information for each case without the need to record information off of every case (Figure 5).

Although the paragraphs below discuss the way a product would be tracked through a facility, it is important to note that lot numbers should also appear on the invoice, bill of lading and/or purchase order or other accompanying or related paperwork, as well as in batching logs and other systems that capture product transformations. Figure 6 shows how a "unique identifier" (akin to a lot number) could be used to follow the path of tomatoes between facilities and during transformations within a facility. It is essential that information that links the movement of product between facilities and within a facility is captured.

If the product was used to make a new product, either in the case of a manufactured food with several ingredients or in the case of repacked product consisting of several inputs, the new product would have a new unique lot number that was linked to the input numbers. This may be expressed as a one-to-one, one-to-many, or many-to-one relationship. The panel believes that this linkage, which provides internal product tracing, is critical in aiding the timeliness and accuracy of product tracing. Reliance on mass balance and theoretical yields was deemed insufficient for tracking. The assumption that an ingredient is brought to a production floor and used does not provide a definitive link between the lot number of the ingredient and finished product lot.

If the product was not used to make a new product, a new lot code would not be necessary as long as there was accurate recordkeeping detailing the lot numbers received and shipped, and linking lot numbers to documents such as invoices and bills of lading. The assignment of a new "lot" number could hinder traceback and trace-forward investigations because of the confusion associated with assigning multiple identifiers to the same manufactured lot of product.

Currently, particularly in the produce and foodservice and retail distribution industries, it is a common practice to assign an internal lot number to a pallet or even a shipment. Challenges to this practice arise when the new "lot" (typically identified at the pallet level) contains cases with more than 1 lot. The practice of assigning a "lot ID" to *more than 1 lot, as identified by the supplier of the product*, must be discontinued as it prevents internal tracing. Still, the panel believes that the continued use of an item

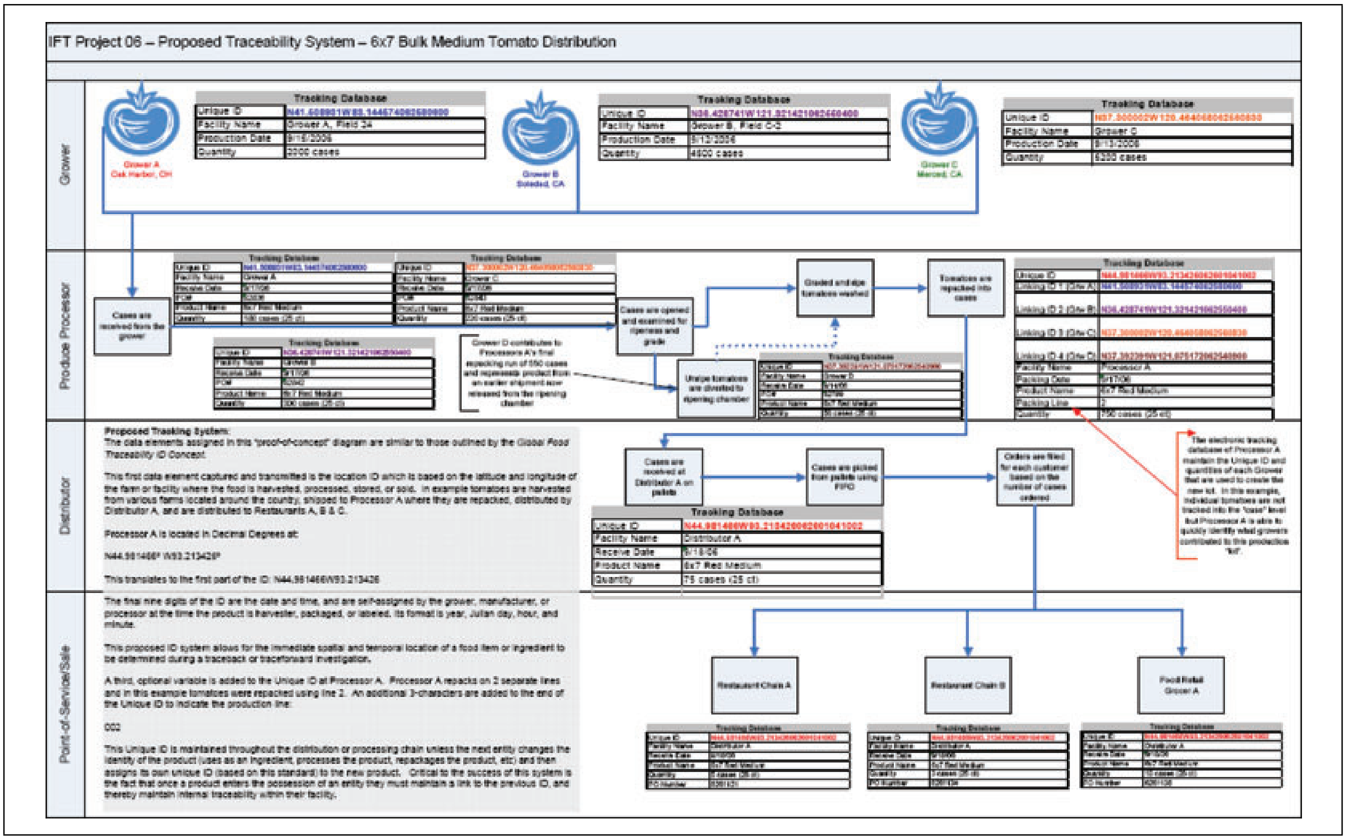

Figure 6—Illustration of how multiple ingredients/inputs (in this case tomatoes) could be identified and tracked through the supply chain.

number or other internal identifier could be done appropriately, as long as it was linked to the production lots as identified on each case. If a pallet comprised of cases with different lot numbers is divided into cases, simply providing the various locations that received cases from the pallet (for example, the recipients), without indicating which lot was shipped to each location, results in a loss of product tracing. In the case of a mixed pallet, shipping records must show where cases with different lot numbers were sent.

If the product was divided into smaller units, a new lot code would be applied, but would still be linked to the original number. If the consumer unit is a packaged product, any lot code appearing on the consumer unit package should be identical to the lot code on the case.

10.3.5 Changing industry practices. Many firms we spoke to indicated that they have voluntarily begun changing practices in response to the tracing issues associated with recent outbreaks. Some of these practices, which we encourage, are:

1. Limiting the number of lots that are combined during operations such as repacking.
   a. Several individuals said that while they continue to repack for quality reasons, they use product from the same lot. Therefore, the size of the repacked lot is less than or equal to the size of the original lot.
2. Limiting the number of suppliers of specific products.
   a. Although we envision that each ingredient that is used in the production of another product would be tracked, limiting the number of suppliers of that ingredient is beneficial.

10.4 Cost-benefit of product tracing

10.4.1 Barriers to implementation. During the course of discussion with industry representatives, they were asked to cite any barriers to enhancing product tracing at their firm. Although they were not provided with any examples or direction, there were several barriers that were commonly mentioned. These are summarized in Table 12.

Not surprisingly, cost was cited most commonly, and by at least 1 representative of each sector, as a barrier. However, it is interesting to note that most firms expressed willingness to make enhancements to their systems if they knew definitively what was expected. The types of costs were sometimes specifically identified, and most often included the need to change their internal computing systems, the cost of scanners and other hardware, and the cost of labor to record data. Less common were the need to redesign processes to include a "step" to provide a label, and references to decreased production speed due to the need to label and/or scan each case. Another consideration regarding scanning cases is that most employees in DCs are unionized, and that contracts may need to be renegotiated. Although types of costs were specified, an estimate of cost was seldom known. Because of the PTI, the produce industry had a better sense of the nature and magnitude of costs for product tracing components, such as the cost to obtain a GTIN.

A barrier IFT often observed was custom-designed IT systems and legacy systems. In a surprising number of cases,

Table 12—Factors cited as barriers to product tracing.

	Cost[a]	No info from suppliers	No supplier interest	No customer interest[b]	Bulk/ commingling challenges	No standard system or expectation[c]	Human element-language, training	No need	*N*[d]
Animal feed	1			2	1	1			3[e]
Ingredient	2								4
Processor	1				1				8
Retail	4	1	3	3		1	1		6
Foodservice–store level	3	1	1				2	2	5
Foodservice–corporate level	2	1	2		1	1	2		5
Produce–grower	2				1	2	1		5
Produce–processor	4		1		2	1			12
Produce–distributor[f]	2	2	3	1	1	1		1	5
All segments	21	5	10	6	7	7	6	3	53[g]

[a]Cost includes hardware, software (and other changes to an internal system), increased labor, and decreased rate of production.
[b]For most segments, this refers to their customer, not a consumer. For retail and foodservice, this refers to consumers.
[c]Includes the need to comply with varying customer requirements.
[d]N = number of companies in that segment.
[e]Participants were asked to cite any barriers to implementation and could name as many as they wished. They were not provided with any examples or direction.
[f]Includes produce wholesalers and distributors, including terminal market wholesalers.
[g]Distributors were not included, nor were one retailer, one animal feed representative, for lack of availability and applicability.

companies utilized more than 1 electronic system, but their systems in a single facility had to be manually linked (for example, one system would be searched, and the "output" would be manually entered in another system to obtain additional information). Other technological barriers included issues with building infrastructure—in some locations, particularly older terminal markets, internet availability is lacking.

Another issue that emerged dealt with suppliers. There was a sense that suppliers were not interested in product tracing, and either did not provide information that enabled product tracing, or provided markings that could not be interpreted by the receiver (and therefore, were often not captured at all). Related to this was an oft-cited frustration with the lack of standardization of information. Participants complained that different customers had different requirements, and the supplying companies often provided varying types of information in varying formats to satisfy the demands of different customers.

There was an overwhelming willingness to enhance the ability to trace products, but a fear that "early adopters" would be penalized in the short and long terms. Many individuals felt they would lose customers to competitors who could offer products at a cheaper price since they did not have costs related to product tracing. There was an agreement that a level playing field with uniform application of product tracing standards was necessary. One retailer was concerned that some of his smaller produce suppliers would not be able to comply with industry standards, and that there would be limited competition for and supply of some produce products as a result.

Some individuals we spoke to expressed that they did not capture or transmit key data elements since others in the supply chain did not, although they recognized that product tracing cannot be accomplished without full participation from all supply chain members. Their sense was, "Why should I invest in product tracing if it doesn't matter anyway?" Many were not willing to change their systems or practices for fear that the expectations or standards would change over time. They clearly conveyed that they would make changes only after a regulation was issued (although they feared that a "solution" would be imposed upon them), or after it was clear how a product tracing system needed to function.

Even if clear, standardized expectations were established, there was concern that much of the data capture would rely on workers. Language barriers and the need for extensive and ongoing training were cited as additional barriers. Some firms, especially small ones, have an aging workforce who may not have the knowledge or dexterity to use computerized systems such as bar codes and readers.

Although not captured in the table, "solution providers" also cited reasons they felt that greater strides in product tracing have not been seen. Some suggested that increased product tracing results in increased responsibility. While a benefit to product tracing in a particular company is the opportunity to rapidly know that its product is not associated with a problem, the converse is true. The ability to trace product results in a loss of anonymity. If a company's product is in fact associated with a problem, this will quickly become evident.

"Solution providers" felt that the lack of enforcement of the BT Act, and restrictions associated with it, resulted in complacency on the part of the food industry. We were told "it's what you inspect, not what you expect." Outside of regulatory enforcement, we also heard concern and confusion regarding the ability of private firms to audit for product tracing. Since there are not currently standard, accepted criteria with which to comply, the ability for firms to audit or monitor others in their supply chain is restricted.

10.4.2 Motivators for product tracing. Many companies saw benefits related to improved product tracing. The ability to trace product was often a benefit associated with improved inventory control. Since the cost of some raw materials is high, there is an increased need to account for them, and not waste them.

Some companies also expressed concern that if the food industry, or their industry segment, did not demonstrate improved product tracing, regulations would be imposed. Most firms we spoke to preferred that the industry devise a solution, and recognized that this would need to occur proactively.

Food safety was often mentioned during discussions with companies. Although Table 12 showed that some firms felt consumers were not interested in product tracing, there was a sense that the ability to trace products would translate into consumer trust and confidence in the food system and their brand in particular.

Traceability "solution providers" offered that improved product tracing provides increased marketing opportunities. Traditionally, the food industry has not viewed food safety as a competitive advantage, and few food companies related product tracing to marketing opportunities. Most saw product tracing as the "cost to do business."

An oft-heard benefit of product tracing is the ability to pin point problems more rapidly and precisely. Solution providers suggest that the scope of a recall can be limited through product tracing. However, we found that improving the speed or scope of a recall was not deemed a motivator, since most firms do not believe that they will have a recall. Only 2 companies, both in the produce industry, cited this as a benefit of product tracing.

10.4.3 Economic impact of product tracing. Reducing the time required before an intervention is implemented following a triggering event, such as an outbreak, will better protect public health, help reduce the economic hardship faced by affected industries, and maintain consumer confidence in the U.S. food supply following such an incident.

Information collected through discussions with the food industry representatives showed that most firms have adopted various types of warehouse management systems. These systems provided product tracing information that varies widely in breadth, depth, precision, and accessibility to other members in the supply chain. Many companies consulted consider product tracing an integral part of their warehouse management, logistics, or accounting initiatives. Therefore, they assign costs related to these business operations to product tracing. Although many of these costs cover product tracing, they are not limited to items related specifically to product tracing. Also, firms may often overlook costs associated with the additional demands for data collection and recordkeeping, and especially the additional labor required. Consequently, product tracing costs, as assigned by participating companies, vary widely and tend to be over- or underestimated. Additional discussions were conducted with providers of various technologies that support product tracing systems.

Developing estimates of the costs to firms of product tracing systems requires estimates of both fixed and variable costs of the systems. At this time, many firms have incurred some of the costs, but estimates of other costs may be prospective. The types of costs firms incur associated with product tracing include capital investment and start up costs; costs of software and associated fees and equipment; external consultant costs; labor (including training); materials and supplies; and other direct costs generated by changes in the harvesting and processing process to support or operate the product tracing systems. The costs may also include changes in operational efficiency. Many of the firms suggested that the implementation of product tracing systems, or an upgrade of their existing practices, could result in additional costs or lower margins for their firms. Firms' representatives expressed that these costs are multiplied and margins lowered even further if multiple customers require different standards for their own product tracing initiatives.

Although each case is unique, case examples described in Volume 2 of this report (Economics Report) show representative costs for 2 cases: one based on the experience in fresh produce following the 2006 *E. coli* O157:H7 outbreak related to spinach, and the other based on costs incurred and expected by a firm that processes and distributes fresh produce and product in a regional market. The 1st case study shows that although the costs of product tracing systems can be significant to the industry, the benefits of more rapid trace-forward following a triggering event may be greater than the costs in a given year. The 2nd case example finds costs to be significant (about 1% of the product value), but viewed by the firm as value added to the type of product they sold. Their major concern was loss of market share if others did not employ similar product tracing systems. The results of the studies indicate that the losses to the industry and to the public in terms of public health were significant in the event of an outbreak. These examples suggest that, although there is some uncertainty that accompanies the estimates presented, the benefits of improved product tracing could outweigh the costs to industry and society in implementing a product tracing system. Firms that have implemented effective product tracing systems find benefits in improved supply chain management, inventory control, access to contracts and markets by having stronger product assurances, more targeted recalls and hence lower costs to recall, and other cost savings incurred during a foodborne illness outbreak. Product tracing systems may help compartmentalize and reduce the region or type of product at risk of recall. Firms could also benefit by protecting brand name, maintaining consumer confidence, and reducing possible liability claims. Especially important is being able to be excluded from the problem. These benefits are dependent on firm, product type, and other factors.

Despite significant firm level and aggregate benefits, the costs of enhanced product tracing can be considerable. Firms that use paper-based and manual entry systems to track incoming supplies or outgoing shipments, and firms that have relatively complex systems where many inputs are processed into products, could face added costs to increase their recordkeeping capabilities. Small- and medium-size enterprises may face particular challenges in meeting new product tracing requirements as they may lack adequate capital, labor, and technology expertise to implement electronic product tracing systems. Research will be required to assess the needs as well as strategies for small- and medium-size firms to develop effective product tracing systems.

Some of the additional costs associated with having improved product tracing capacity could be transferred—from firms to consumers. The private benefits to a firm incurred through the capacity for improved product tracing may be dissipated if its customers do not value these additional capabilities, and are not willing to pay these costs. Firms could become less competitive than other companies that do not have product tracing systems in place. Any failure in being able to trace 1-step back and 1-step forward, as well as link the movement of product internally, in a 24 h period will undermine the effectiveness of the product tracing system and limit its efficacy in the case of product recall. Thus, the cooperation of all links of the supply chain will be necessary for a product tracing system to be successful. A more rapid response to an accidental or intentional foodborne disease through improved product tracing would yield external social benefits beyond the direct benefits and cost reductions to the firms. Additional healthcare costs, social losses, loss of life, loss of consumer confidence, major psychological and emotional damages due to massive outbreaks, and indirect loss in economic output and productivity losses are just the most evident externalities that could be avoided with a functional product tracing system.

11.0 Research Needs and Future Work

Through discussions with nearly 200 individuals representing almost 60 food companies and more than a dozen technology providers, as well as numerous trade associations and others, we were able to highlight some key observations and provide recommendations to improve product tracing. However, 60 food companies are not representative of the entire food system, and additional work, dependent on segment/commodity and point in the supply chain needs to be undertaken to have a better understanding of issues and practices in any 1 particular area of the food industry.

Further, the heightened awareness around product tracing has resulted in several industry-led initiatives. These should be closely monitored, and FDA should be involved as partners and collaborators so as to avoid duplication or wasted efforts. Industry should seek and FDA should provide feedback on these types of initiatives.

Because the food system is global, any product tracing system should take into consideration pertinent developments of international bodies, such as texts produced by Codex Alimentarius. Considerations at national levels should commence in the near term, to minimize conflicts with requirements of different countries and prevent multiple standards and regulations that need to be adhered to by food producers and handlers.

Although this study provided a very broad look at product tracing in the food industry, it did not address or only touched on some segments of the food industry and supply chain, such as seafood, food banks, brokers, and others. Since product tracing is relevant to all industries and at all points in the supply chain, these areas and other sectors are worthy of future study.

Another area that warrants further exploration is the mechanism by which FDA has access to or obtains key data elements. Investigation of the application of existing FDA electronic portals, such as the Reportable Food Registry and Facility Registration, to product tracing, should take place. Several types of data collection systems were discussed in this report, but additional expertise is needed to gain a clearer understanding of technological capabilities and feasibility for both industry and FDA. The opportunity for FDA to remove information related to firms deemed to not be associated with a triggering event from final traceback reports should also be explored.

Additionally, how FDA performs data analysis when data are obtained still requires additional work and exploration. Task Order 7 began to address this issue and the technology issues mentioned previously; however, a variety of technology providers offer services, many of which feature "visualization" as a component of their analysis system, and these should be further explored.

The smaller- and medium-size enterprises may face particular challenges in meeting new product tracing requirements. Small- and medium.size enterprises lack adequate capital, labor, and technology expertise to implement electronic product tracing systems. Furthermore, there is apprehension of electronic systems and their potential for failure. Research that assesses the needs as well as strategies for these firms to develop effective product tracing systems will be required.

Finally, while communication and collaboration between regulatory authorities and the regulated food industries appear to be increasing, some misunderstand or are not aware of certain industry standards, regulations, or best practices. A substantial investment in the development of guidance materials, with a well thought out plan to disseminate these materials, particularly to small and very small businesses, as well as to regulators, is critical for improvements in product tracing. Ideally, this training would occur within educational and training venues.

12.0 Conclusions

The complexity of the food system cannot be overemphasized. Compared to nonfood industries, the food supply chain has an enormous number of contributors around the globe, who handle a wide variety of products that may or may not be combined, recombined, and reconditioned before reaching consumers.

The benefits of product tracing may be dependent on or correlated with the nature of the product under investigation. For example, in the instance of a perishable product, testing of the finished product at retail, or an outbreak that prompts an investigation may have little public health benefit if the contaminated product is beyond shelf life and is no longer being consumed. On the other hand, the benefits of the ability to trace backward and forward, from the perspective of public health, may be greater for products with longer shelf life, and if they are used as ingredients since the ability to stop the consumption of contaminated products may be more likely. It should be recognized that even in the former example of perishable products, the ability to understand circumstances leading to contamination may result in the development of mitigation strategies that will serve as preventive controls in the future.

Members of the food industry employ a variety of systems and processes to ensure an efficient supply chain. Many of these systems, used both within a firm and between trading partners, were not developed to provide uniform, global product tracing, but most have the capacity to capture key data elements and therefore lend themselves to product tracing.

CTEs are those instances where product is moved between premises or is transformed, or is determined to be a point where data capture is necessary to maintain the ability to trace products through the supply chain. In many instances, the use of paper-based recordkeeping was observed and reported, even within larger companies, for some CTEs. While various mechanisms can be used to provide effective recordkeeping within a facility and to communicate information between trading partners, to expedite traceback investigations, key data elements that link the flow of product between as well as within facilities for CTEs must be determined and provided to FDA in an electronic format within 24 h of a request.

Information can easily be queried and scenarios can be tested when quality data are available in electronic formats. In order for the challenges associated with sorting through paper to be reduced, electronic data should be accepted by FDA. Representatives from several firms expressed frustration at not receiving follow up from federal or state regulators when responses to requests for information or for product samples were provided. It is hoped that the ability to review information quickly and easily will facilitate the opportunity for regulators to "close the loop" with information providers.

In order for FDA to be able to analyze information, and to facilitate communication and comprehension between supply chain members, globally recognized standardized formats of data should be used. If a limited set of standards are acceptable, they should be compatible with each other. Requiring one company to provide data in multiple formats, as is currently the case, complicates product tracing.

Product tracing in the food industry is under scrutiny and the industry seems aware of this, as is reflected in the several industry initiatives are underway to address product tracing, and some companies are conducting their own feasibility studies. The practices observed during the course of this task are likely to change in the coming months or years as product tracing systems evolve and are enhanced. Current work by private companies, industry trade associations, consortiums, and solution providers should be recognized and encouraged, and partnership and collaboration between all stakeholders, including regulators, must continue and improve so that issues are clearly understood so that any progress made to date is further improved upon. Firms providing the required product tracing and following the recommendations proposed are likely to be at a disadvantage in some markets if the product tracing is not universally required of all firms.

The recommendations provided in this report may be easy for some firms to implement; others may need to modify their handling and recordkeeping practices. It is expected that these adjustments may take additional time and resources, and that the time to achieve full implementation may vary. It should be recognized that costs will be incurred on a daily basis, even though events that trigger the need for product tracing data may occur infrequently.

Because the BT Act of 2002 restricts FDA's access to industry records, it is important to verify, outside of an investigation, that appropriate records are maintained. There first needs to be substantial training on recommended practices, and consensus on definitions. It was clear that different firms use similar terms to express very different practices. Both industry and regulators need to work together and attend joint training sessions to achieve a common understanding of what is required to quickly and effectively conduct a product traceback. Reaching a clear understanding of what is expected, particularly for small operators and those who are exempt from the BT Act, will be critical. Once the expectation for product tracing is agreed upon, mechanisms should be developed to check compliance, such as incorporation into inspections and audits.

Ultimately, tracing products occurs in a system, not in a firm alone. However, no product tracing system can be effective without product tracing in place at the firm level.

13.0 References

African Food Safety and Traceability Conference. April 2007. Available from: www.tanzaniagateway.org/.../Kenya_AfricanFoodSafetyTraceabilityConference.pdf. Accessed Jul 29, 2009.
AIM Global. 2005. RFID hacking threat overstated. Available from: http://www.aimglobal.org/members/news/templates/template.aspx?articleid=292&zoneid=24. Accessed Aug 20, 2009.
AIM Global. 2009. What is RFID? Available from: http://www.aimglobal.org/technologies/rfid/what_is_rfid.asp. Accessed Jul 29, 2009.
Arens S. GS1 US. 2009. Personal communication.
BRC Global Standards. 2009a. The BRC global standard for food safety Issue 5. North American edition. Available from: www.brcglobalstandards.com/standards/food/. Accessed Aug 3, 2009.
BRC Global Standards. 2009b. BRC best practice guideline: traceability—issue 2. Available from: www.brcglobalstandards.com/index.cfm?page=417. Accessed Aug 4, 2009.
CAC. 2006. Principles for traceability/product tracing as a tool within a food inspection and certification system. CAC/GL 60-2006.
CAC. 2008. Codex Alimentarius Commission. Procedural Manual 18th Ed. Joint FAO/WHO Food Standards Programme. World Health Organization/Food and Agriculture Organization of the United Nations. Rome.
CAC. 2009. ALINORM 09/32/REP. Report of the Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. 32nd Session, Rome.
Camire K, Spencer S. 2009. Less than 20% of consumers trust food they buy is safe and healthy, IBM survey reveals. IBM. Available from: http://www-03.ibm.com/press/us/en/pressrelease/27817.wss. Accessed Sept 15, 2009.
Campden BRI. 2009. Traceability in the food and feed chain: general principles and basic system requirements. Guideline nr 60. Gloucestershire, U.K: Campden BRI.
Canadian Food Inspection Agency. 2008. Available from: http://www.inspection.gc.ca/english/anima/trac/traccane.shtml. Accessed Jul 7, 2009.
Can-Trace. 2009a. Self assessment tool. Available from: http://www.can-trace.org/selfassessmenttool/introduction.asp?langid=e. Accessed Aug 20, 2009.
Can-Trace. 2009b. About Can-Trace. Available from: http://www.can-trace.org/AboutCanTrace/tabid/73/Default.aspx. Accessed Aug 20, 2009.
Can-Trace. 2009c. Reports. Available from: http://www.can-trace.org/REPORTS/tabid/81/Default.aspx. Accessed Jul 7, 2009.
Can-Trace. 2006a. Canadian food traceability data standard Version 2.0. Available from: http://www.can-trace.org/portals/0/docs/CFTDS%20version%202.0%20FINAL.pdf. Accessed Aug 20, 2009.
Can-Trace. 2006b. Can-Trace completes second version of Canadian food traceability data standard. 2 Aug 2006 Press Release. Available from: http://www.can-trace.org/MEDIAROOM/PressReleases/CanTraceCompletesSecondVersionofCanadianFoo/tabid/123/language/en-US/Default.aspx. Accessed Aug 20, 2009.
CASAGRAS. 2008. CASAGRAS partners agree vision statement and definition for internet of things. CASAGRAS an EU Framework 7 Project. Media Information for Immediate Release. 11 Dec 2008. Available from: http://www.rfidglobal.eu/press/Casagras%20-%20Shanghai%20release.pdf. Accessed Aug 20, 2009.
CCFICS. 2008. ALINORM 09/32/30. Report of the seventeenth session of the codex committee on food import and expert inspection and certification systems. Cebu, Philippines: CCFICS.
CDC. 2008. *Salmonella* outbreak investigations: timeline for reporting. Available from: http://www.cdc.gov/salmonella/reportingtimeline.html. Accessed Aug 20, 2009.
Chartier P, Van Den Akker G. 2008. GRIFS Global RFID Forum for Standards. D1.3 RFID standardisation state of the art report—Version 1. Available from: http://www.grifs-project.eu/data/File/GRIFS%20D1_3%20State%20of%20the%20Art%20Report.pdf. Accessed Aug 20, 2009.
Comparative analysis of food and nutrition policies in WHO European Member States. 2003. Available from: http://www.docstoc.com/docs/2410607/Comparative-analysis-of-food-and-nutrition-policies.
Consultation on the Improvement of the Food Control System in Albania. Nov. 2008.
Decision News Media SAS. 2009. Food Ingredients & Food Science. 2009. Available from: http://foodnavigator.com/content/view/print/247123. Accessed Jul 7, 2009.
European Commission. 2007a. Food traceability. Health & Consumer Protection Directorate-General. Available from: http://ec.europa.eu/food/food/foodlaw/traceability/factsheet_trace_2007_en.pdf. Accessed Aug 20, 2009.
European Commission. 2007b. TRACES: trade control and expert system. Health & Consumer Protection Directorate-General. Available from: http://ec.europa.eu/idabc/jsps/documents/dsp_showPrinterDocument.jsp?docID=5377&lg=en. Accessed Aug 20, 2009.
European Commission. 2007c. Food traceability. Health & Consumer Protection Directorate-General. Available from: http://ec.europa.eu/food/food/foodlaw/traceability/factsheet_trace_2007_en.pdf. Accessed Aug 20, 2009.
FAO/WHO Global Forum of Food Safety Regulators. 2004. Strengthening official food safety control services: risk management approach - imported food control—a success story. Available from: http://www.foodsafetyforum.org/global2/crd_en.htm. Accessed Jul 29, 2009.
[FDA] U.S. Food and Drug Administration. 2006. Investigations operations manual. Available from: http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf. Accessed Aug 19, 2009.
FMI Media: News Release. 2009. FMI grocery shopper trends 2008: economic concerns shaping how consumers shop, cook and dine. Available from: www.fmi.org/news_releases/index.cfm?fuseaction=mediatext&id=935. Accessed Sept 10, 2009.
Food Processing. 2007. Survey reveals eroding consumer confidence in packaged goods brands. Putman Media. Available from: http://www.foodprocessing.com/industrynews/2007/093.html. Accessed Dec 20, 2008.
FoodTrace. 2009. Available from: http://www.eufoodtrace.org. Accessed Aug 20, 2009.
GAO. 2008. Food safety: selected countries' systems can offer insights into ensuring import safety and responding to foodborne illness. Available from: http://www.gao.gov/htext/d08794.html. Accessed Nov 23, 2009.
Greener Choices. 2008. Food-Labeling Poll 2008. Consumer Reports Research Center. Available from: www.greenerchoices.org/pdf/foodpoll2008.pdf. Accessed Sept 15, 2009.
GS1 US. 2009a. Available from: www.GS1US.org. Accessed Aug 21, 2009.
GS1 US. 2009b. GS1 global traceability standard. Available from: http://www.gs1.org/traceability/gts. Accessed Aug 21, 2009.
GS1 US. 2009c. Products and solutions. Available from: http://www.gs1.org/productssolutions. Accessed Aug 21, 2009.
GS1 US. 2009d. Global activities. Available from: http://www.gs1.org/traceability/activities. Accessed Jul 29, 2009.
GS1 US. 2009e. Traceability. standards knowledge center. Available from: http://www.gs1.org/gsmp/kc/traceability. Accessed Jul 29, 2009.
GlobalGAP. 2009. Available from: http://www.globalgap.org/cms/front_content.php?idcat=9. Accessed Sept 15, 2009.
GRIFS. 2009. European Commission. Available from: http://www.grifs-project.eu/. Accessed Jul 29, 2009.
Haberkorn J. Business News. 2007. Food recalls damage consumers' confidence in safety. The Washington Times. Available from: http://washingtontimes.com/news/2007/jul/05/food-recalls-damage-consumers-confidence-in-safety/. Accessed Sept 10, 2009.
Houses of the Oireachtas. 2009. Current traceability system for Irish Pork not adequate and new system urgently needed-Oireachtas Agriculture Committee Report. Available from: http://www.oireachtas.ie/viewdoc.asp?DocID=11910. Accessed Jul 13, 2009.
Hu J-I. 2009. Development of Gap and traceability system for greening the food chain in Taiwan. Food and Fertilizer Technology Center. Available from: http://www.agnet.org/library/eb/592/. Accessed Jul 29, 2009.
IBM. 2008a. IBM and Matiq to develop first of a kind tracking solution for the Norwegian food industry. Oslo, Norway. Available from: http://www-03.ibm.com/press/us/en/pressrelease/24595.wss. Accessed Aug 21, 2009.
IBM. 2008b. IBM and Matiq to develop first of a kind tracking solution for the Norwegian food industry. Oslo, Norway. Available from: http://www.-3.ibm.com/press/us/en/pressrelease/24595.wss. Accessed Aug 21, 2009.
[ICMSF] Intl. Commission on Microbiological Specifications for Foods. 2002. Microorganisms in foods 7: microbiological testing in food safety management. [Section 6.1]. New York: Kluwer Academic/Plenum Publishers.
[IFDA] Intl. Foodservice Distribution Assn. 2009. Foodservice distribution: connecting the foodservice industry. Available from: http://www.ifdaonline.org/webarticles/anmviewer.asp?a=622&z=38. Accessed Jul 28, 2009.
IFIC. 2009. Consumer and opinion leader research. "2009 Food & health survey: consumer attitudes toward food, nutrition & health." Available from: www.ific.org/research/foodandhealthsurvey.cfm. Accessed Sept 15, 2009.
IFS. 2003a. Available from: http://www.ifs-online.eu/. Accessed Jul 28, 2009.
IFS. 2003b. Available from: http://www.ifs-online.eu/index.php?SID=68054d2b419d7e29dc92dfdc7fd435eb&page=home&content=public_content&desc=download&direct_count=. Accessed Jul 28, 2009.
IFS. 2003c. Frequently asked questions. Available from: http://www.ifs-online.eu/index.php?SID=68054d2b419d7e29dc92dfdc7fd435eb&page=home&content=faq&desc=. Accessed Jul 28, 2009.
Institute of Food Technologists. 2009. Contract Nr 223-04-2503 for FDA. Task Order Nr 6, Traceability in Food Systems. Vol. 2. Economics Report.
IPFSAPH. 2009. Traceability. Available from: www.ipfsaph.org/servlet/CDSServlet?status=ND1jdGh0dHB3d3dmYW9vcmdhb3NpcGZzYXBoaXNzdWVrZXl3b3Jkc3RyYWNlYWJpbGl0eSY2PWVuJjMzPSomMzc9a29z. Accessed Sept 15, 2009.
Labuza T. 2008. Personal communication. Univ. of Minnesota. Dec. 8, 2008.
Lee C-H. 2007. Traceability for agri-products in Korea. Food and Fertilizer Technology Center. Available from: http://www.agnet.org/library/bc/54015/. Accessed Jul 29, 2009.
Manufacturingtalk. 2006. Traceability the key to effective safety testing. Available from: http://www.manufacturingtalk.com/news/clh/clh128.html. Accessed Jul 7, 2009.
Marler B. 2007. Consumer confidence in food supply drops. Food Poison Blog. Available from: http://www.foodpoisonblog.com/2007/08/articles/food-poisoning-watch/consumer-confidence-in-food-supply-drops/. Accessed Dec 20, 2008.
Matsuda T. 2009. Gap as a baseline, traceability as a pipeline to build consumer confidence. Food and Fertilizer Technology Center. Available from: http://www.agnet.org/library/bc/54001/. Accessed Jul 29, 2009.
Mccombie W, Welt BA. 2009. Radio-frequency identification (RFID). The Wiley Encyclopedia of Packaging Technology. Available from: http://www.wiley.com/WileyCDA/WileyTitle/productCd-0470087048,descCd-description.html. Accessed Sep 29, 2009.
[NZFSA] New Zealand Food Safety Authority. 2008. Importing—food importer standards guidance. Available from: http://www.nzfsa.govt.nz/importing/food-importer-standards-guidance/page-02.htm. Accessed Aug 28, 2009.
[NZFSA] New Zealand Food Safety Authority. 2009a. New Zealand Food Safety Authority. Available from: http://www.nzfsa.govt.nz/. Accessed Aug 28, 2009.
[NZFSA] New Zealand Food Safety Authority. 2009b. Draft Identification and Traceability. Available from: http://www.nzfsa.govt.nz/policy-law/projects/domestic-food-review/custom-fcp/identification-and-traceability_fcp.htm. Accessed Aug 28, 2009.

[NZFSA] New Zealand Food Safety Authority. 2009c. Apiarist and beekeeper statement for the harvest of honey and other bee products for human consumption. Available from: http://www.nzfsa.govt.nz/animalproducts/legislation/notices/export/harvest-statement-june-2009.pdf. Accessed Aug 28, 2009.
OIE. 2009a. Recommendations. International Conference on Animal Identification and Traceability. Available from: http://www.oie.int/eng/traceability-2009/documents/recommendations/ENG-%20Recommendations.pdf. Accessed Aug 20, 2009.
OIE. 2009b. General recommendations: Disease prevention and control. Terrestrial Animal Health Code. Available from: http://www.oie.int/eng/normes/mcode/en_titre_1.4.htm. Accessed Sept 15, 2009.
OIE. 2009c. OIE International Conference on Animal Identification and Traceability. Available from: http://www.oie.int/eng/traceability-2009/documents.html. Accessed Jul 29, 2009.
PAHO. 2009. Available from: http://www.paho.org/English/DD/AIS/cp_124.htm. Accessed Aug 28, 2009.
PETER. 2009. Available from: http://www.eu-peter.org/. Accessed Jul 29, 2009.
Produce Traceability Initiative. 2009. PTI Action Plan Implementation Toolkit. Available from: http://www.producetraceability.org/. Accessed Jul 31, 2009.
RFID Journal. 2009. The basics of RFID technology. Available from: http://www.rfidjournal.com/article/articleprint/1337/-1/1. Accessed Jul 8, 2009.
RFID News. 2009. Vietnamese agency seeks seafood traceability. Available from: http://www.rfidnews.org/2009/05/18/vietnamese-agency-works-toward-seafood-traceability. Accessed Jul 29, 2009.
Reiback MR, Simpson PND, Crispo B, Tanenbaum AS. 2006. RFID Viruses and Worms. Vrije Univ. Amsterdam. Available from: http://www.rfidvirus.org/ Accessed Aug 20, 2009.
Sayler A. 2009. IDFA, Personal communication, August 19, 2009.
SQF Inst. 2009. Available from: http://www.sqfi.com. Accessed Sept 15, 2009.
State of Queensland. 2005. Stock Identification Regulation 2005. Available from: http://www.legislation.qld.gov.au/LEGISLTN/SLS/2005/05SL101.pdf. Accessed Aug 28, 2009.
State of Queensland. 2009. Food Production (Safety) Regulation 2002. Available from: http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/F/FoodProdSafR02.pdf. Accessed Aug 28, 2009.
Stenzel T. 2009. Testimony to the House of Rep, Committee on Appropriations, Subcommittee on Agriculture, Rural Development, FDA and related agencies, March 26, 2009.
Texas Instruments. 2009. ExxonMobil Speedpass. Available from: http://www.ti.com/rfid/shtml/apps-contactless-speedpass.shtml. Accessed Jul 29, 2009.
TRACE. 2009. Tracing the Origins of Food. Available from: http://www.trace.eu.org. Accessed Aug 20, 2009.
TraceFood Wiki. 2009. Available from: http://www.tracefood.org/index.php/Main_Page. Accessed Aug 20, 2009.
TraceTracker. 2008. Available from: http://www.tracetracker.com/cgi/news.cgi?id=212. Accessed Oct 22, 2009.
UNSPSC. 2009. Available from: http://www.unspsc.org/. Accessed Aug 20, 2009.
USDA. 2009. Food "tattoos": an alternative to labels for identifying fruit. Available from: http://www.ars.usda.gov/is/pr/2009/090831.htm. Accessed Jul 8, 2009.
Warranty Week. 2003. Don't TREAD on me. Available from: http://www.warrantyweek.com/archive/ww20030331.html. Accessed Jul 8, 2009.
Weier MH. 2008. Wal-Mart sets deadline for Sam's Club suppliers. RF Edge. Available from: http://www.rfid.world.com/205904108?printableArticle=true. Accessed Aug 20, 2009.
Welt B. 2009. Personal communication. Univ. of Florida.

14.0 Glossary

Access: The speed with which track and trace information can be communicated to supply chain members and the speed with which requested information could be disseminated to public health officials during food-related emergencies. (FDA task order 6 scope of work)

Batch: Procedure used to draw or constitute a sample. (Codex Alimentarius)

Bill of lading: A legal contract between a carrier and a shipper that provides shipment details for the movement of freight. (GS1 US Glossary)

Breadth: The amount of information the traceability system records. (FDA task order 6 scope of work)

Codex Alimentarius: Collection of internationally adopted food standards in a uniform manner. (Codex Alimentarius)

Co-op: A member-owned business. Surplus revenue is returned to the member-owners proportionate to their use of the cooperative. A consumer-owned cooperative typically buys produce, and so on from processors and food producers, including local farms; a producer-owned cooperative is owned by the growers, or producers themselves.

Co-manufacturer: A co-manufacturer transforms food products but does not own the brand name, processes and/or specifications applied to the product. It is a supplier of finished goods typically on a contract agreement. (GMA Food Supply Chain Handbook)

Core Expert Panel: Group of 7 individuals with expertise in traceability systems, recalls, retail, and so on assisting IFT with Task Order nr 6, Traceability in Food Systems

Critical Tracking Events: Points where product is moved between premises or is transformed, or is determined to be a point where data capture is necessary to maintain traceability.

Depth: How far upstream or downstream in the supply chain the system tracks. (FDA task order 6 scope of work)

External Traceability: The data exchange and business processes that take place between trading partners to accurately identify (track/trace) product. (GS1 US Glossary)

Food-Related Emergency: As determined by a district director of FDA due to the likelihood of serious adverse consequences or death to humans or animals. States have different authority as well.

Global Location Number (GLN): The globally unique GS1 System identification number for locations such as manufacturing facilities, headquarters, DCs, stores, hospitals, and so on.

Global Trade Item Number (GTIN): The globally unique GS1 System identification number for products and services. A Global Trade Item Number may be 8, 12, 13, or 14 digits in length, represented as GTIN-8, GTIN-12, GTIN-13, and GTIN-14 respectively. (GS1 US glossary)

Brand owners provide and maintain GTINs to buyers. They may be human and machine-readable.

Internal Traceability: The ability to follow the path of a specified unit of a product and/or batch within one company or company unit. (CIES)

When a traceability partner receives one or several instances of traceable items as inputs that are subjected to internal processes, before one or more instances of traceable items are output. (GS1 US Glossary)

Lot: A definite quantity of some commodity manufactured or produced under conditions, which are presumed uniform. (Codex Alimentarius)

Smallest quantity for which a firm keeps records. (USDA)

Price Look-Up Code (PLU): Common to the retail industry; in the produce industry it refers to the 4/5 digit number on loose produce items; in other retail categories it refers to UPCs and/or SKUs as a numeric method to look up price information in scanning systems or through electronic cash registers/systems.

Point of Service Location: Location where product can be purchased by a consumer. Typically refers to a foodservice operation where food has already been prepared and is ready for immediate consumption.

Point of Sale: Location where product can be purchased by a consumer. Refers to a retail checkout where bar code symbols are normally scanned. (GS1 US Glossary)

Precision: The degree of assurance with which the system can pinpoint a particular product's movement or characteristics. (FDA task order 6 scope of work)

Product Tracing: The ability to trace potentially contaminated product, the consumption of which may cause an adverse health impact, through the supply chain.

Recall: Procedure to withdraw food from the market where food has left the immediate control of that initial food business and where the product may have reached the consumer. (CIES)

The removal and/or correction of marketed products that are in violation of federal or state laws. (GMA Food Supply Chain Handbook)

Repacking: When a person other than the original packer repacks a product into another container. (USDA)

Retail: Involves the sales of foods in supermarkets and shops and in the informal sector, such as street-food vendors and market stalls. (WHO)

Rework: Wholesome, salvageable product generated during a production run that is not acceptable as the approved finished end product on the end product schedule. (USDA)

Supply Chain: The system of organizations, people, activities, information and resources involved in producing and/or moving a food product to the consumer. (GMA Food Supply Chain Handbook)

Traceability: The ability to follow the movement of a food through specified stage(s) of production, processing, and distribution. (Codex Alimentarius)

Traceability can be done for several purposes, including the tracing of genetically modified organisms. Therefore, the term "product tracing" may more accurately reflect what is meant when traceability is used in the context of traceback investigations which seek to identify the movement of contaminated product, the consumption of which may have an adverse health impact.

Traceback Investigation: Starts with the consumer or the point-of-purchase and traces the distribution of the product back to the source/farm. This is the process used in response to a foodborne illness outbreak.

Traceforward Investigation: Begins with the source/farm or manufacturer/distributor and traces forward to the consumer. This process is used for a product recall and it can also be useful in outbreak investigations.

Transformation Point: Point at which there is change to the nature of a traceable item that changes the identity and/or the characteristics of the traceable item. (GS1 US Glossary)

Whole-Chain Traceability: Internal + External traceability. (GS1 US Glossary)

WMS: Warehouse management system.

Appendix A. IFT Staff and Core Expert Panel

Staff Personnel

Project Director. Jennifer Cleveland McEntire, Ph.D., IFT Research Scientist and Manager, Science & Technology Projects

McEntire served as the Project Director and facilitated the Expert Panel's deliberations, managed implementation of the work, provided technical support to the panel's activities, coordinated day-to-day project activities, and managed preparation of the final report, achieving completion of activities throughout the 12-mo contract period while ensuring the scientific and technical integrity of the project.

Expertise: McEntire has expertise in food safety, food microbiology and food defense, training in physical security and classification, and experience working with groups of scientific and technical experts to produce scientific and technical documents, with organizational administration (for example, personnel, project oversight, and other issues and procedures); and with Federal requirements of contracting and subcontracting personnel.

Staff Scientists. Rosetta Newsome, Ph.D., IFT Director of Science and Communications

Dr. Newsome worked in concert with the Senior Science Advisor, Project Director, and other staff scientists to support the panel's deliberations, enabling successful completion of the scope of work, facilitating the scientific and technical integrity of the resulting reports. Newsome also contributed to report preparation and deadline compliance.

Expertise: Extensive knowledge of the farm-to-table food system; in-depth knowledge of food science and technology; expertise in food safety, food defense, and food microbiology; and substantial experience in project direction, communications, and working with scientific and technical expert panels and consultants to analyze food-related issues and produce scientific and technical documents.

Betty Bugusu, Ph.D., IFT Research Scientist

Dr. Bugusu assisted the Project Director, Senior Science Advisor, and others with scientific aspects of the project, enabling successful completion of the scope of work. Dr. Bugusu specifically led the systems and technologies subpanel, and led many of the discussions with the food industry members, particularly in the foodservice segment.

Expertise: Knowledge of food science and technology, food chemistry, nutrition, food nanoscience, and food product packaging.

Sarah Davis Ohlhorst, M.S., R.D., IFT Staff Scientist

Sarah Ohlhorst worked with the Project Director, Senior Science Advisor, and others with scientific aspects of the project, enabling successful completion of the scope of work and facilitating the scientific and technical integrity of the resulting reports. Specifically, she led many of the discussions with solution providers and food industry representatives. She also assisted the Project Director with organizational administration and providing administrative support to the Expert Panel and the project.

Expertise: Knowledge of food science and technology, food chemistry, nutrition/dietetics, CARVER + Shock assessment and software, food defense, food allergen manufacturing and labeling practices, and working with groups of scientific and technical experts to produce scientific and technical documents.

Carla Mejia, Ph.D., IFT Research Scientist.

Dr. Mejia began working on this task in January 2009. She led the cost evaluation subpanel, and also analyzed data from the discussions with food industry members.

Administrative Assistants. Jacqueline Heppes and Erin Carter

Heppes was responsible for making all meeting arrangements, including hotel accommodations for panelists and subpanelists, ordering refreshments, and processing expense vouchers through June 2009, after which Carter handled these functions.

Project Development Analyst. William Fisher

Fisher provided broad oversight on this task and provided strategic direction when needed. He assisted the Project Director and core expert panel in the development of recommendations and best practices, and provided critical review of all final reports.

Additional Assistance. Brittany Kenah, student, Virginia Tech (IFT intern summer 2008 and winter and summer 2009)

Kolade Osho, currently with Natl. Milk Import Federation (IFT intern fall 2008)

Sarah Scholl, currently graduate student (IFT intern summer 2008)

Core Expert Panel

Senior Science Advisor. Frank F. Busta, Ph.D., IFT Senior Science Advisor

Dr. Busta worked with the Project Director, Expert Panel, and other IFT staff to successfully complete the project. Dr. Busta assisted with Panel deliberations and contributed food safety, food defense, and other relevant expertise to the panel discussions and other activities.

Expertise: Director Emeritus, The Natl. Center for Food Protection and Defense, A Homeland Security Center of Excellence, Professor Emeritus, Food Microbiology and Emeritus Head of Dept. of Food Science and Nutrition, St. Paul, Minn., U.S.A. Busta has experience in food microbiology, particularly spore-forming bacteria; biochemistry; traditional and alternative processing technologies and their impact on microbial injurious agents; food safety management systems; food defense; and food industry familiarity.

As described previously, IFT consulted with a core expert panel comprising expertise and experience in food production/distribution/retail, food microbiology, food toxicology, epidemiology, risk assessment, economics, infrastructure analysis, biosecurity, intelligence, and computer programming. The individuals who served on the expert panel are summarized below: In addition, subpanels were formed to address specific issues. These are listed below:

Systems and Technology subpanel: evaluated "solution providers" and technological aspects of traceability.
IFT staff leader: Betty Bugusu
Core panel liaisons: Steve Arens and Gale Prince
Subpanel members: Marc Bernstein, IFT; Bruce Welt (Univ. of Florida)

State Traceback subpanel: Provided feedback on applicability of draft recommendations.
IFT staff leader: Sarah Ohlhorst
Core panel liaison: Ben Miller
Subpanel members: Pat Kennelly, California Dept. of Public Health; Wendy Campbell, Washoe County (Nevada) Health District; Kathleen Hanley, North Carolina Dept. of Agriculture; Jill Ball, Wisconsin Dept. of Agriculture, Trade & Consumer Protection

Food Industry Subpanel: Provided feedback on draft recommendations
IFT staff leaders: Jennifer McEntire and Sarah Ohlhorst
Core panel liaisons: Frank Busta and Gale Prince
Subpanel members: Sarah Geisert, General Mills; Brenda Lloyd, UFPC; Robert Mills, Tanimura and Antle; Dan Sutton, Albertsons LLC

Cost Evaluation subpanel: Identified types of fixed and variable costs, assigned values, and generated cost evaluation report
IFT staff leader: Carla Mejia
Core panel liaison: Helen Jensen
Subpanel members: Kevin Keener, Purdue Univ.; Mary K. Muth, RTI Intl.; William Nganje, Arizona State Univ.; Thomas Stinson, Univ. of Minnesota

Appendix B. Flow of Conversation with "Solution Providers"

Date, participant name, and IFT representative's names
Summary
Technology description
Interoperability
Use in food systems
COOL
Cost consideration
Future advancements
Security

Appendix C. Discussion Questions for State Traceback Investigators

1. From a regulatory standpoint, what are some of the key challenges in conducting a traceback investigation?
    a. Does this document adequately address those concerns and if not, do you have specific recommendations for improvements?
2. Are there elements in these draft recommendations that will enhance your ability to conduct traceback investigations?
3. Are there elements in the draft recommendations that may hinder your ability to conduct trackback investigations?
4. Do these draft guidelines have the potential to improve trace-forward or effectiveness check activities and if so, what elements will help in this effort?
5. From a regulatory standpoint and in your opinion, what factors are most important in improving food traceability in the United States?

Appendix D. Complete Discussion Document

Institute of Food Technologists
Traceability Discussion Document

Introduction

The Institute of Food Technologists, the 22000 member scientific and professional society for food scientists and technologists, is performing a task contracted by the U.S. Food and Drug Administration to assess and evaluate industry practices with respect to traceability. As part of this work, we are speaking with select members of the food industry, representing a variety of products (packaged, nonpackaged, ingredients, and so on) and working at various stages of the supply chain (from point of production to point of service) to learn about practices currently in place.

Our final report to FDA will provide aggregate information; information specific to an individual or company will not be disclosed. Please review the topics below that may be covered during our discussion. We hope the conversation will be somewhat informal—we want to hear about what you are currently doing, what you might be planning on doing, and gather your thoughts on traceability.

We very much appreciate your willingness to work with us! If you have any questions, please don't hesitate to contact the Project Director, Dr. Jennifer McEntire, at 202-466-5980 or by e-mail at jcmcentire@ift.org

Demographic Topics

- Company name
- Company size (based on number of employees, sales, or other)
- Member of a trade association
- Position in the company
- Years employed
- Number of facilities company has in the United States, and overseas
- Percentage of facilities located overseas
- Types of food products company manufactures/handles
- Nature of the business (direct to store delivery, to warehouse, retailer, shelf stable products, co-packer, and so on)
- Number of *food* SKUs are manufactured (or for retail, handled in a given store)
- Products unbranded, branded, or both
- Number of cases of the product we are considering are manufactured per unit time (day, week, and so on)
- Average case cost of merchandise

General (including motivation for traceability, who has access to traceability info, and so on)

- Traceback responsibility and management
    - Responsibility for collecting and maintaining the product information
    - Sharing of traceability information

Name	Role as expert panelist; basis for selection	Affiliation
Martin Cole, Ph.D.	Strong background in scientific research with extensive international experience at a senior level within industry, government, and academia.	Executive Director, Natl. Center for Food Safety & Technology, Illinois Inst. of Technology, Ill., U.S.A.
Helen Jensen, Ph.D.	Expertise in consumption economics, food and nutrition policy, agricultural economics, human resources, and econometrics. Led economics subpanel.	Professor, Dept. of Economics, Iowa State Univ., Ames, Iowa, U.S.A.
Stephen Arens, MBA	Works with the food industry to implement GS1 standards to improve the efficiency and visibility of supply and demand chains globally and across sectors. Provided consulting on bar codes, RFID, UNSPSC, and so on.	Senior Director, GS1 US, N.J., U.S.A.
Benjamin Miller, MPH, RS	Training and experience in epidemiology, with 1st-hand knowledge of tracebacks. Understanding of food systems as well as state and local government capabilities. Solicited and summarized feedback from state traceback investigators.	Operations and Response Section Manager, Minnesota Dept. of Agriculture, Minn., U.S.A.
Arthur Davis, Ph.D.[a]	Extensive traceability, supply chain, and quality expertise in the produce and baking/cereal industries.	Vice President/Operations, The Sholl Group/Green Giant Fresh, Minn., U.S.A.
Gale Prince, B.S.	Broad and extensive commodity product, food manufacturing, distribution, and retail expertise with one of the nation's largest multi-state grocery retailers. Advanced knowledge of quality and safety of food during manufacturing, distribution, retail; crisis management. Organized many "field trips" and provided additional consulting.	SAGE Consulting, LLC; Ret., Director, Corporate Regulatory Affairs, The Kroger Co., Cincinnati, Ohio, U.S.A.
Brenda Lloyd[a]	Deep knowledge of logistics, supply chain operations, and traceability systems. Broad knowledge of foodservice supply chain. Served as food industry subpanel member before joining core expert panel.	Director, Distribution Systems, UFPC, LLC, Ky., U.S.A. (purchasing group for Yum! Brands)

[a]Dr. Davis served as a member of the core expert panel until July 1, 2009, when his affiliation changed. At that time, Brenda Lloyd, who had contributed to the task nearly from the beginning, was invited to contribute to the core expert panel.

- Types of traceability practices
  - One-step forward, one-step back
  - Different for national/overseas facilities
  - Country of origin
- Number of suppliers dealt with on a regular basis
  - Source from where you receive ingredients from (direct from company, from distributor/broker, and so on)
  - Receiving rules and verification of paper or electronic documents, lot codes
- Traceability requirements necessary for suppliers
  - Ingredients imported or sourced from overseas- information received via prior notice documentation
  - Audit traceability for suppliers
  - Risk assessment of ingredients
  - Handling, requirements, and traceability of those identified as "risky"
- Pressure from suppliers to have a traceability system in place (or to convert to an alternate system), or touting theirs
- Pressure from customers to have a traceability system in place (or to convert to an alternate system)
  - For retail- interest in COOL
  - For manufacturers- where are requests coming from
- Traceback of raw ingredients
  - Lot numbers on incoming ingredients (handwritten, entered into computer, scanned)
  - Tracking of which batches ingredients go in to (who is responsible)
- Ingredient storage
  - Off-site at a 3rd party logistics or similar facility
  - In bulk or packaged- difference in traceability
  - Different lots/batches stored in bulk containers (silos and so on)
  - Procedure to break the chain of commingling (such as cleaning, complete emptying, and so on)
- Rework
  - Traceability
  - Unique lot code
  - Treated like an ingredient
- Frequency of inventory checks
  - Reordering of ingredients
- Other traceability practices not utilized by your company
  - Commercial products, brands that fit your needs
  - Potential effectiveness
- Barriers that have kept your company from implementing certain traceability programs
  - Possible solutions
- Use of re-packers, consolidators, brokers
- Pathogen testing
  - Impact to movement of products (hold times, and so on)
- Attachment 5 of the FDA Guide to Traceback Fresh Fruits and Vegetables Implicated in Epidemiological Investigations (source: http://www.fda.gov/ora/Inspect_ref/igs/epigde/epigde.html)

How traceability information is collected and stored

- Identifier on a pallet, case, or unit or bulk transport product that is received
  - Nature of that identifier (Bar code, RFID, microprint, other)
- Capture the information of incoming material (handwritten, typed into computer, scanning, and so on)
  - Assign new lot codes for ingredients
  - Internal lot code bar coded or linked to original shipment from supplier
- Handheld bar code readers
- Information storage
  - Storage location (for example, your own system or a 3rd party)
  - Readily accessible is the information
  - Length of retention
- Traceability through internal inventory, shipping, or other systems
- Use of programs offered by traceability solutions providers (like software programs)
  - Number of providers
  - In-house written traceability programs
  - Evaluations of effectiveness of traceability programs
- Costs for capital equipment improvement, additional record-keeping
- Bar codes on finished products

How quickly can traceability information be accessed, retrieved, and reported?

- Past product recalls
  - Resulting changes
  - Time required for traceback, trace forwards
  - Amount or affected product recovered
  - Mock recalls
- Crisis communication plan
  - Updates

Commodity specific retailer

- Loyalty cards/membership cards
- Customer contact during recall
  - Loyalty card information, website, cash register tapes, shelf signs, bulletin board, or other methods
- Recalls
  - Who has responsibility
  - Situations for Class I recall
  - Verification of product removal
  - Identification of recalled product (for example, scan gun to verify U.P.C.)
  - Bill back recalled product to the supplier
- Changes to your system needed if each product has unique ID
- Scanning Device
  - Use in receiving merchandise and document quantity
  - Use in shipments
- Store invoices
  - Lot codes information contained
  - Estimated number of packing slips received
  - Identification- lot or shipper ID
- Current method of tracking lot codes of finished products
  - Scanning of products by store
  - Storage of lot codes- duration of records, paper, or electronic
- Purchase of fill-in products from wholesale membership warehouses (Costco, BJs, and so on, farmers markets, terminal markets, co-ops, and so on)
  - Frequency of purchases
  - % of product

Produce

- Use of temperature monitors in shipping
  - Effect on implementing traceability initiatives
- Type of packing/handling is performed on your product (for example, field pack, shed pack, or processed)
- Sale of split/partial cases of fresh produce
- Sales at terminal markets, co-ops, and so on
- Reuse of bins/boxes/and so on reused, regardless of brand
  - Effect of ability to distinguish them
- Commingling of various brands
  - Effect of ability to distinguish them
- Use of re-packers, consolidators, or brokers
- Use of electronic sorting of produce
- Knowledge of PTI
  - Estimated cost of implementation for your company
- Costs of the harvesting and processing improvements to assist in traceability systems

Foodservice

- Number of suppliers used for food products/ingredients
- Location of shipped ingredients before receipt at an individual store (food distributor, company-owned warehouse, supplier, and so on)
- Tracking of what lots of product are used in specific stores in specific days
- Reuse of bins/boxes/and so on reused, regardless of brand
  - Effect of ability to distinguish them
- Commingling of various brands
  - Effect of ability to distinguish them
- Sale or purchase of split cases of fresh produce
- Purchase of fill-in products from wholesale membership warehouses (Costco, BJs, and so on, farmers markets, terminal markets, co-ops, and so on)
  - Frequency of purchases
  - % of product

Other economic and cost considerations

- Cost of implementing one up/one back traceability after to the BT Act
- Possible further enhancements
  - Costs
  - Increased labor
  - Plans to pass some or all of those costs on to your customer
- Readable bar codes with lot numbers built in to them

  - Effect on saving costs
- Other benefits, economic or otherwise, to having improved traceability (reduced liability, QC, marketing)
- Customer interest in knowing where a product and its ingredients came from

Attachment 5: interview questions

In the July 1998 Traceback Guide, a questionnaire was completed and included in the final reports. This questionnaire is no longer required. However, many investigators have found these questions useful for eliciting information, so they are included here as a reference.

POS event information

1. Product preparation date/time (a.m./p.m.):
2. Have there been any reports of illness to the POS?
3. Were any of your employees ill during the 2 weeks prior to the event?

Outgoing deliveries to customers and incoming deliveries from suppliers

1. Can the source of implicated product delivered to customers be tracked precisely by the use of a lot numbering system?
2. How are **customer deliveries** documented or recorded?
3. Are the outgoing delivery records initialed or stamped with the delivery date?
4. How are **supplier deliveries** documented or recorded?
5. Are the records of an incoming shipment initialed or stamped with the receipt date?
6. If the records don't reflect receipt dates, explain how should the recorded dates be adjusted to reflect receipt dates (for outgoing shipping dates and incoming shipment receipts)?
7. Were there any holidays or unusual occurrences that would have affected delivery or receipt dates?
8. What are the transit times from each of the supplier(s) listed above to the current establishment?
9. Are there any transfers of products within the company? How are these handled and documented?

Shipping and receiving practices

1. When and how does the firm order new stock?
2. Is there a standard stock "low point" after which the firm orders additional product?
3. What happens if the firm does not have enough product to fill an order?
4. What are the firm's stock rotation practices?
5. Are the stocking practices generally followed at this establishment? When might they be deviated from?
6. Is a stock inventory taken? How often and what time of the day is inventory taken?
7. At what time does this establishment load its deliveries to customers?
8. If inventory is taken, is it taken before or after deliveries for the day are loaded?
9. If inventory is taken, is it taken before or after shipments are received?
10. Did the customer(s) pick up the order or was it delivered?
11. What are suppliers' general delivery times?

Product handling and storage practices

1. Does the firm have an SOP and documentation for rejected or returned products?
2. Does the firm have an SOP for disposal of product too old to sell?
3. Is the product prepared, repackaged and/or handled prior to distribution, service, or sale?
4. How is the customer product loaded?
5. Does the firm mix loads?
6. Is there an SOP for loading?
7. Does the firm have an SOP for truck cleaning or specifications for acceptance of vehicles for loading?
8. Is it clear to the loaders which product should be loaded first?
9. What are the approximate shipping times to the firm(s) who received the implicated product?
10. How is the incoming product handled upon receipt?
11. Do suppliers use any chemical or gas treatment on the product before shipping?

Appendix E. Shortened Discussion Document

Institute of Food Technologists
Traceability Discussion Document

Introduction

The Institute of Food Technologists, the 22000 member scientific and professional society for food scientists and technologists, is performing a task contracted by the U.S. Food and Drug Administration to assess and evaluate industry practices with respect to traceability. As part of this work, we are speaking with select members of the food industry, representing a variety of products (packaged, nonpackaged, ingredients, and so on) and working at various stages of the supply chain (from point of production to point of service) to learn about practices currently in place.

Our final report to FDA will provide aggregate information; information specific to an individual or company will not be disclosed. Please review the topics below that may be covered during our discussion. We hope the conversation will be somewhat informal—we want to hear about what you are currently doing, what you might be planning on doing, and gather your thoughts on traceability.

We very much appreciate your willingness to work with us! If you have any questions, please don't hesitate to contact the Project Director, Dr. Jennifer McEntire, at 202-466-5980 or by e-mail at jcmcentire@ift.org

The following is a list of topics that may be covered—we will not necessarily address every item during the conversation:

- Basic company info
  - Types of food products company manufactures/handles
  - Number of SKUs manufactured (or for retail, handled in a given store)
- Number of suppliers dealt with on a regular basis
  - Type of ingredients source (direct from company, from distributor/broker, and so on)
  - Receiving guidelines and document verification (paper or electronic, lot codes, and so on)
- Identification of received material
  - Form of packaging (pallet, case, unit, or bulk)
  - Nature of identifier [Bar code, RFID, microprint, other]
- Capture of information of incoming material (Handwritten, typed into computer, scanning, and so on)
  - Assignment of new lot codes for ingredients
  - Internal lot code bar coded or linked to original shipment from supplier
- Ingredient use and handling

  - Tracking of which batches ingredients go in to
  - Different lots/batches stored in bulk containers (silos and so on)
  - Procedure to break the chain of commingling (such as cleaning, complete emptying, and so on)
- Traceback responsibility, accountability, and management
  - Responsibility for collecting and maintaining the product information
  - Sharing of traceability information up and down supply chain, and with regulators
- Use of re-packers, consolidators, or brokers
- Rework
- Commingling of various brands/lots
  - Effect of ability to distinguish them
- Bar codes on finished products
- Past product recalls
  - Resulting changes
  - Time required for traceback, trace forwards
  - Amount or affected product recovered
  - Mock recalls
- Cost of implementing one up/one back traceability after to the BT Act
- Possible further enhancements
  - Costs
  - Increased labor
  - Plans to pass some or all of those costs on to your customer
- Other benefits, economic or otherwise, to having improved traceability (reduced liability, QC, marketing)
- Customer interest in knowing where a product and its ingredients came from
- Barriers that have kept your company from implementing certain traceability programs
  - Possible solutions

Appendix F. Examples of GS1 Traceability Activities around the World

Brazil: Developed traceability guidelines for fresh produce and meat.
Canada: Working with Can-Trace on a collaborative and open initiative to develop traceability standards for all food products grown, manufactured, and sold in Canada. The "Traceability Center of Expertise" was developed in collaboration with 11 solution providers, to provide webinars, demo seminars, education, and knowledge transfer to the Canadian industry.
Costa Rica: For which fruit export is a major activity, developed with the government the Traceability Conformance Program for the agro food sector to assist exporters in implementing traceability and comply with the EU and U.S. requirements.
Egypt: Cooperated with the Egyptian Natl. Center for agro food traceability (E Trace), funded by the United Nations Industrial Development, to assist farmers and exporters to implement traceability and comply with the requirements of EU regulation Nr EC178/2002.
France: Conducted a study which showed that beyond ensuring consumer safety and respecting laws, food supply chain traceability programs lead to measurable business benefits and return on investment.
Guatemala: Approached several sectors to work on traceability projects for sugar, coffee, and lemons; and incorporated traceability projects at the master's level in universities.
Mexico: Generating 15 pilot tests on traceability based on the Projects of the Free Trade between the European Community and Mexico for products including shrimp, pigs, birds, and avocados.
Peru: Developed and implemented projects in sectors including bananas, organic coffee, herbs, wine, olives, asparagus, and fishing.
Switzerland: Using traceability to fight counterfeit pharmaceuticals.
Thailand: Working with the Dept. of Livestock Development to encourage use of GLN for traceability; assisting the private sector with software development.
United States: Established a collaborative effort with FMI and GMA on a standards-based food recall system to solve a critical problem of structured messaging and workflow aligned with global supply chain standards.[1]
Vietnam: Working with Shrimp Traceability Pilot Project sponsored by the government to encourage use of GS1 keys and standards.

Appendix G. Participant List

Solution providers, trade association, and food industry representatives who provided IFT with information were promised anonymity. However, some wanted their participation to be acknowledged, so IFT offered all contributors the opportunity to be listed below. Therefore, this list represents only those firms who opted in, and does not represent the complete list of contributors to the task. These contributors have not necessarily seen any portion of the report, and their presence on this list does not constitute agreement with any findings presented in this study.

[1] https://www.srmregistration.org/

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World Food Trace, Inc.	Paul Nowicki President and Co-founder, World Food Trace, Inc. 919-720-1405 pnowicki@worldfoodtrace.org www.worldfoodtrace.org
Bruce A. Welt, Ph.D.	Bruce A. Welt, Ph.D. Associate Professor Univ. of Florida/IFAS Gainesville, FL 32611-0570
Wegman Food Markets, Inc.	Kathleen O'Donnell Chief Food Scientist Wegman Food Markets, Inc. 585-429-3623

Appendix H. Poll Results from IFT Traceability Webcast

In January 2009, IFT held a live webcast for 53 sites (note: an additional 20 sites accessed the webcast on-demand). Registration was open to anyone, not just IFT members and not just those in the food industry. Registrants were asked to answer a brief demographic survey prior to participating, and 27 individuals completed it. The results are below:

1. What industry are you in?

Manufacturing	55%
Distribution	10%
Retail	3%
Government	0%
Academia	17%
Service Provider/Consultant	7%
Other	7%

2. Where in the world do you live?

USA	86%
North/Central America (non-US)	10%
South America	0%
Europe	3%

3. Have you ever participated in a mock recall?

Yes	52%
No	48%

4. If yes, how often (please choose closest answer)?

Monthly	0%
Quarterly	22%
Annually	28%
> Annually	22%
Once	6%
Other	22%

5. Have you ever been part of an actual recall?

Yes	41%
No	59%

A portion of the webcast was used to acquire information to inform this task. Participants were asked questions and presented with options to select from. The results are presented here; however, the answers are not linked with the specific individuals who responded, and the participants may not be representative of the food industry at large. Of the 53 participating sites, the number who answered each question varied, presumably depending on whether they felt the question applied to them. Still, it is interesting to compare perceptions to reality to regulation in this limited pool.

First, participants were asked, "From the time a product is implicated in an outbreak, how quickly should you be able to trace a product from source (point of production) to point of service/sale?" The response was:

1 d	74%
1 wk	11%
2 wk	7%
1 mo	4%
2 mo	3%
3 mo	0%
>3 mo	1%

The BT Act of 2002 requires 1-step forward, 1-step back recordkeeping, but does not specify or limit the total sum of time within which the full farm-to-point of sale/service chain needs to be known. Clearly, respondents felt that a rapid trace was important and should be expected.

"If a regulatory agency asked for all of your suppliers of a specific ingredient or product, and all recipients and lot numbers of product made from it, how long would it take to provide that information?"

1 h	7%
Half day	27%
1 d	30%
2 d	27%
4 d	2%
1 wk	5%
1 mo	0%

It is striking when comparing the response to this question to the response to the previous question that while participants felt the full chain should be known within 1 d, only about a third of respondents could provide information for their part of the chain in less than 1 d, and more than a third would need more than 1 d to provide the 1-up, 1-back information. Again, it should be noted that the participants may or may not be required to provide this information under the BT Act recordkeeping requirements.

Many of the companies who sell traceability systems to the food industry tout the marketing aspects of traceability. Some even provide a website where consumers can enter information about the product and learn where and when the product was harvested. With that in mind, we asked participants, "Do you think some or most consumers care where their food comes from?"

Yes	89%
No	2%
Maybe	8%

Traceability is wholly dependent on recordkeeping. We asked, "When you receive a product/ingredient, do you track the incoming lot #?"

Yes	85%
No	11%
It depends	2%

It should be noted that we did not ask how a lot was assigned or defined, what system was used to track the lot number, and other important information. Therefore, it is possible, and from the in-depth conversations we had with food industry representatives perhaps likely, that traceability is not possible or is not rapid just because incoming lot numbers are tracked. It is also somewhat surprising that in a webcast about traceability, more than 10% of respondents report that they do not track incoming lot numbers.

Often discussions on traceability tend to focus on the paper compared with electronic records debate. We wanted to find out what form of systems and records are used most prevalently in the food industry. "For traceability, do you:"

Currently use an electronic system	66%
Plan to use an electronic system	33%
Do not plan to use an electronic system	3%

As evidenced by the next question, the definition and application of an "electronic system" varies from firm to firm.

"When it comes to invoices, bills of lading, receiving tickets, etc., what form are they in?"

Paper	29%
Electronic	3%
Mostly paper/some electronic	32%
Mostly electronic/some paper	35%

As we also found in our interviews, a mixture of paper and electronic records is predominantly used in the industry, and paper-only records are still used by many firms. Many firms are starting to use electronic labeling to record traceability on containers, even if they still use paper records.

"What kind of labeling do you currently use for outgoing shipping containers?"

RFID	0%
Bar codes	73%
Both	10%
Other systems	16%

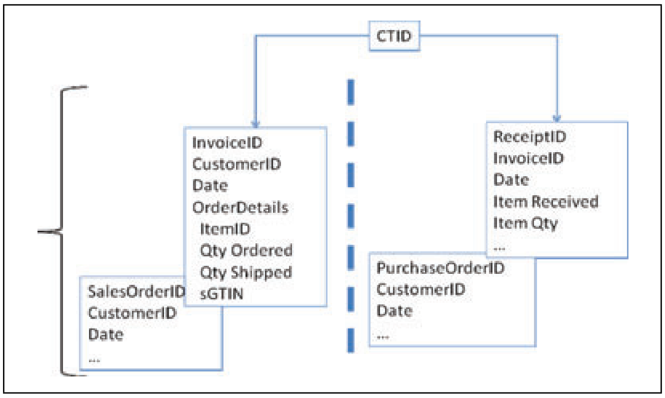
Appendix I. Critical Tracking Identifier

The panel deliberated whether key data elements needed to be communicated between supply chain partners, or if a single, critical traceability identifier (CTID), was sufficient to serve as a "pointer" to key data elements. Although the recommendations contained within this report support the transfer of key data elements, the CTID concept is presented in more detail here.

Critical tracking events (CTE) are those events that must be recorded to allow for effective traceability of products in the supply chain. CTEs can be loosely defined as a transaction. Every transaction involves a process that can be separated into a beginning, middle, and end. While important and relevant data may exist in any of the phases of a CTE transaction, the entire transaction may be uniquely identified and referenced by a code referred to as a critical tracking identifier (CTID). As an example, the transfer of pallet-loads of food from one company to another may involve creation of sales orders, production orders, shipping manifests, advanced shipping notices, bills of lading and receiving tickets, invoices, and payments. Each of these items represents a portion of the overall transaction and each may provide important pieces of data in the event of a traceability exercise or recall event. Use of a unique transaction ID, however, allows for the whole story of the transaction to be captured by 1 unique key, or pointer to all relevant data related to the transaction.

CTIDS simply need to be unique identification codes that point to related data in distributed relational databases. For purposes of data security, CTIDS should not contain any data meaningful or descriptive of the transaction. There are a variety of freely available universal or global code generating algorithms that offer very low probability of duplication. An example is the universal identification system (UID). Microsoft uses such a system to generate global universal identification codes (GUID) for its software.

The CTID is a globally unique identification code that connects existing documents and data into a traceable network.



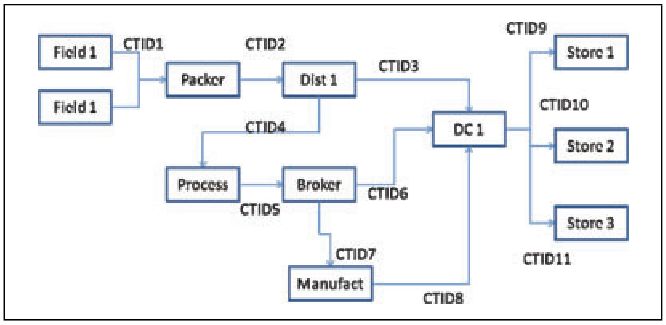
CTEs may be internal or external to the organization. Examples of external CTEs include receiving and shipping. Examples of internal CTEs include batching, aggregating, mixing with other ingredients, transformations, and so on. To enable supply chain tracking, companies must store data related to external CTEs. Within reason, companies could decide on the level of granularity required to record internal CTEs. As depth of internal CTE recording increases, scope of product recalls would decrease.

It is important to recognize that supply chain traceability is a process, not a destination. As a process, it will be subject to refinement and improvement over time as knowledge and technology improve.

To begin development of an effective and self-improving traceability system, the following philosophy is suggested:

1. Companies should analyze their operations to identify CTE that will require definition of CTIDS.
2. Each CTE should be assessed to ensure that data necessary to allow for effective tracking (one-step forward, one-step back) are defined and means are developed to generate CTIDS and capture and store CTE data in a relational database.
3. Companies expose CTIDS to allow for traceability queries, however, companies establish data access permissions and control release of data related to CTIDS. In the event of a traceability query that identifies a CTID, related data may be provided in a manner consistent with a company's business policies and in accordance with requirements of regulatory compliance. The following 2 examples demonstrate methods for delivering data:
   a. Company is notified that a CTID is involved in a traceability query. The company assembles relevant data and submits in an approved manner within a given time frame.
   b. Company establishes prearranged permissions to allow for FDA to extract data related to the CTID.
4. As CTE data are made available, the next CTID or CTIDS become exposed, allowing the traceability query to move along the chain back to the origin.

The following example describes a theoretical situation involving traceability of jalapeno peppers through the supply chain. The fictitious supply chain involves a multi-field farm, packer, distributor, processor, broker, food manufacturer, and supermarket chain. The peppers are sold through the supermarket chain as fresh, dried, and as an ingredient of a frozen pizza.



This example shows 11 external CTEs, each uniquely identifiable with a CTID. Assuming that FDA wishes to investigate the origin and disposition of peppers purchased from Store 2. If the peppers are packaged, a UPC code could be used to expose all CTIDS involving peppers within a certain time frame and investigations would proceed. Assuming there is more identifying information, such as a lot number, FDA could immediately identify CTID10, which is associated with data that contain peppers from a particular lot.

Once CTID10 is established, FDA is able to query DC1, which yields CTID3, CTID6, and CTID8. Since FDA is initially interested in fresh peppers and not dried or as an ingredient, FDA pursues CTID3, which leads to Distributor 1, which exposes CTID2 and the particular Packer that handled the peppers. With this information, FDA can learn the date, time, and fields from which the peppers were harvested.

In the case of a triggering event, FDA could use the links to other transactions involving these peppers to provide targeted recall recommendations to other entities who handled the peppers.