Leafy Greens Action Plan Tech Enabled Traceability

2020 Leafy Green Pilot **FINAL REPORT**

Table of Contents

About GS1 US

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About FMI

As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. *www.FMI.org*

About IFDA

IFDA is the premier trade association for the foodservice distribution industry contributing to the industry's growth, development, and success through our outstanding advocacy, events, research, and education. IFDA's membership includes broadline, systems, convenience, and specialty foodservice distributors that supply food and related products to restaurants, schools, colleges and universities, hospitals and care facilities, hotels and resorts, and other foodservice operations.

About IFT

The Institute of Food Technologists (IFT) is a global organization of approximately 13,000 individual members from across 95 countries committed to advancing the science of food. Since 1939, IFT has brought together the brightest minds in food science, technology and related professions from academia, government, and industry to solve the world's greatest food challenges. Our organization works to ensure that our members have the resources they need to learn, grow, and advance the science of food as the population and the world evolve. We believe that science is essential to ensuring a global food supply that is sustainable, safe, nutritious, and accessible to all. For more information, please visit ift.org.

About PMA

Produce Marketing Association (PMA) is the leading trade association representing companies from every segment of the global produce and floral supply chain. PMA helps members grow by providing connections that expand business opportunities and increase sales and consumption. For more information, visit *www.pma.com*.

About United Fresh Produce Association

Founded in 1904, the United Fresh Produce Association brings together companies across every segment of the fresh produce supply chain, including growers, shippers, fresh cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. We empower industry leaders to shape sound government policy. We deliver the resources and expertise companies need to succeed in managing complex business and technical issues. We provide the training and development individuals need to advance their careers in produce. Through these endeavors, we unite our industry with a common purpose – to build long-term value for our members and grow produce consumption.

1   Summary

This report documents the results of the 2020 Leafy Green Traceability Pilots primarily aimed at testing how industry expertise could help focus an investigation more effectively by gathering pertinent information from supply chain partners that may not always be asked by investigators during tracebacks. The pilots also tested the efficacy of the Produce Traceback Template developed as part of the Romaine Task Force in response to several romaine lettuce foodborne outbreaks.

The report details the purpose, methodology, results, and observations from pilot participants, and lays out recommended next steps to enhance the Produce Traceback Template. It also offers suggestions on additional supply chain information (e.g., sales data, stock rotation) and approaches that may help investigators quickly focus in on shipments and lot codes of interest, which were identified as critical to the success of these pilots.

Each of the three pilot teams, comprised of industry experts, tasked with determining the lot number of a romaine-containing item purchased roughly two months prior using only a shopper card or credit card number and the name of the retail outlet. As the teams uncovered the firms involved in the supply chain, each entity was asked to provide relevant traceback data through the Produce Traceback Template. Note, these pilots were begun prior to the US FDA's issuance of the food traceability proposed rule per the Food Safety Modernization Act. As such, the traceback template and data elements requested were not intended to test data the FDA is proposing as part of the rule. The pilots did identify types of information that can accomplish traceability that are not considered "key data elements" (KDE) or "critical tracking events" (CTE), as those terms are used in the proposed rule.

In summary, the following are summarized findings of the three pilot scenarios and key observations. Please refer to the rest of the document for full details.

Pilot 1 - Branded bagged salad from a regional chain grocery store - By understanding product movement in this supply chain, Pilot Team 1 successfully identified the lot number of the finished product purchased by the consumer and was able to further narrow it down to the timeframe and line of production.
Pilot 2 - Romaine hearts sold at an independent retailer that used a third-party distributor - By understanding product movement in this supply chain, Pilot Team 2 was successful in identifying the 2 lot numbers of the finished product that could have been purchased by the consumer.
Pilot 3 - Private label salad (under USDA jurisdiction) from a national chain store - Due to the fact the product had been out of stock prior to the consumer purchase, this "clean break" allowed Pilot Team 3 to identify two possible finished product lot numbers on the purchase date.

Key observations
1. Utilizing existing product movement information from a supplier (grower or processor) to a distribution center (retailer DC or third-party), to the store, and the sales at the store, were key to focusing the pilot teams on one or two finished product lots that could be purchased. In all three pilots, the industry experts successfully identified the lot number of the purchase. Expanding the inquiry to cover the full shelf life of the product resulted in more complicated traceback diagrams and all three teams independently determined that this approach alone

could not distinguish the product of interest unless additional business intelligence was leveraged.

2. While the template was useful at conveying the necessary traceability data elements to participants and capturing it in summarized form, use of the produce traceback template requires additional training/instructions and more granular guidance to be effective in quickly linking product movement through the supply chain. In addition, pilot participants recommended specific modifications to the template to address challenges uncovered by the pilots, including, but not limited to:
   - Training on use of template
   - Improved definitions for "transformation" events and location identification
   - Better indication of what fields are applicable to all vs. only to certain supply chain roles
   - Standardization of data or drop-down menus for certain data elements
   - Improved ability to automatically link information within certain data fields
   - Removal of data elements in the template that were not used by the expert teams

2   Background

The U.S. Food and Drug Administration (FDA) developed the Leafy Greens STEC (Shiga Toxin Producing *E. coli*) Action Plan, March 2020, to outline deficiencies and opportunities to improve food safety throughout the supply chain. One of the points identified was the need to improve end-to-end traceability throughout the leafy greens supply chain by looking at how industry and the FDA can rapidly trace a contaminated food to its source, which can help shorten outbreaks, narrow product warnings, and prevent illnesses.

In response to FDA's initiatives for improved traceability in the produce supply chain, a diverse group of six associations launched industry-led leafy green traceability pilots. The collaboration among FMI, GS1 US, International Foodservice Distributors Association (IFDA), Institute of Food Technologists (IFT), Produce Marketing Association (PMA), and United Fresh focused on two objectives:

   - Provide industry with better visibility into FDA's Coordinated Outbreak Response and Evaluation (CORE) traceability processes
   - Examine utility of **Produce Traceback Template**, which was an outcome of the 2019 Romaine Task Force (https://www.unitedfresh.org/content/uploads/2019/09/Final-Romaine-Task-Force-Report-9-30-18.pdf)

This Leafy Green Pilot Task Force developed and executed three leafy green traceback pilots. The initial work began the end of July 2020 and concluded at the end of October 2020. To achieve the key objectives above, the Leafy Green Pilot Task Force (Task Force):
   - focused on various romaine-containing products for pilots; consideration for different product/supply chain configurations
   - planned, initiated, and worked with identified volunteers/industry experts to execute each pilot scenario
   - reviewed and synthesized the data in this final report to be shared with the FDA and leafy green stakeholders

The key findings will enable the leafy green industry to better respond to regulatory records requests with the goal of rapidly identifying the origin of the contaminated product and could help the FDA improve their outbreak process

3 Methodology

In June 2020, consumers affiliated with United Fresh Produce Association purchased romaine-containing products from different types of outlets in different parts of the country. The following information was captured for each purchase:

- Date of purchase
- Location of purchase (point of sale/ service name, city, and state)
- Product description (e.g., 3-pack romaine hearts; salad)
- Brand (as applicable)
- Identifying information (as applicable, e.g., UPC, harvest region, lot number)
- Shopper information (e.g., shopper card, credit card)
- Photographs of receipt and product (including identifying information)

After deciding to conduct three separate pilots, the Task Force prioritized the purchases in order to examine the greatest diversity relative to the types of supply chains and complexity of the product. The purchases with the following attributes were ultimately selected for the pilot:

- Pilot 1: regional, self-distributing grocery chain; branded fresh-cut salad blend; shopper card used
- Pilot 2: single location retailer; third-party distributor; branded field-packed romaine hearts; shopper card used
- Pilot 3: national retailer; private label prepared salad (USDA regulated); commissary product; credit card purchase

While the Task Force had several different foodservice and retail scenarios identified, all three pilots were within retail environments.

Each pilot was conducted by a team of industry experts. Each Task Force member identified 1-2 individuals from the industry with extensive experience and expertise in traceability. This spanned experience in responding to data requests during outbreak investigations (both from the food safety and information technology perspectives) and managing traceability data. Individuals were invited to participate based on their expertise, and not because of their organizational affiliations. Prior to working on the pilots, each expert was required to sign a participation agreement on behalf of their company stipulated confidentiality requirements. Experts volunteered their time and were not compensated for their participation.

The teams were composed of the following types of individuals/experts:

- Pilot 1
  - Third-party traceability software solutions and the use of global standards
  - Produce safety and outbreak investigations from the supplier perspective
  - Food safety from the retail perspective
- Pilot 2
  - Third-party traceability software solutions and the use of global standards
  - Produce safety during distribution
  - Foodservice supply chain traceability
- Pilot 3
  - Food safety from the retail perspective
  - Foodservice supply chain traceability
  - Information technology for produce growers

Different combinations of three Task Force members took on the role of monitoring teams as they conducted the traceback. Each expert team received a one-hour orientation from the association

partners reviewing their roles, the traceback template and user guide, onboarding letter for supply chain members, expectations, and deliverables.

As a condition of participating in the pilots, each supply chain member was required to sign the participation agreement/non-disclosure agreement (NDA). The association partners were successful in ensuring that each point of sale signed the NDA prior to the start of the pilot. However, it was not always obvious which companies (distributors, processors, growers) were part of the supply chain. Each entity needed to sign an NDA before the expert teams provided them with a data request. The impact of this approach on the timely completion of the pilots is detailed within each pilot summary.

To begin the pilot exercise, each team received an email containing the following information:
- That the hypothetical outbreak implicated romaine as a vehicle (i.e., other ingredients should not be traced)
- The rough date of illness onset (weekend of June 27)
- Shopper card number (pilot 1); shopper name and phone number with which to find the shopper card info (pilot 2); shopper name from which to find credit card info (pilot 3)
- Store name, city, and state

The degree to which the association team interacted with the pilot team varied between the three pilots. Team 1 provided updates upon request; the association partners scheduled regular check-ins with teams 2 and 3.

Pilot team 1 created a tracking document to capture the progression of the pilot (e.g., when certain data were requested, from whom, time to respond). This was adopted and utilized by the other two teams.

The amount of time that each pilot team spent orienting the supply chain partners with the template also varied. Expert teams required supply chain members to share the requested traceback information via the template (e.g., as opposed to providing Bills of Lading and/or Purchase Orders, that contained the relevant data). Each pilot team stitched the data in the templates together in order to develop a traceback diagram. The traceback diagram began with the single point of sale and included, in a redacted form, the various supply chain members that ultimately traced back to the farms, ranches, and lots that could have been purchased by the consumer. The traceback teams were encouraged to ask the supply chain members for any additional information to help them identify, with as much specificity as possible, the origin of romaine purchased by the consumer.

Following the conclusion of each pilot team's work and review by the association partners, the FDA independently created the traceback diagrams based on the redacted data in the templates. The association partners met with Agency representatives on a weekly basis. The names of the experts in the pilot teams and the companies and individuals involved in the traceback were not shared with FDA. The association partners removed all identifiable information from the completed traceback templates, anonymizing and genericizing as necessary, and shared the templates with FDA so that the agency could see if the data could be mapped into a database, and if the supply chain linkages and resulting traceback diagram could be recreated.

At the conclusion of each pilot, the association team held a briefing call with the pilot experts. Then, one member of the association team followed up with one member of the pilot team and separately, one member of the supply chain, and gathered more detailed feedback using a standardized discussion guide. The results of each pilot were synthesized from the data in the tracking document, group discussions with the pilot team, individual discussions with members of the pilot teams and supply chain participants, and our own observations.

4 Leafy Green Pilots

4.1 Pilot 1 - Branded bagged salad from a regional chain grocery store

4.1.1 Timeline and Results

Pilot one, tracing a single purchase of a branded bagged salad from a regional chain grocery store, began on August 11. The team successfully identified the single finished product lot purchased by the customer on September 13. Although it appears that it took over a month to complete the traceback, this timeframe included an 8-day delay while waiting for the fresh-cut processor to receive and then sign the NDA, and both the retail and fresh-cut processor key contacts had vacations during this timeframe. In actuality, the Pilot Team 1 had collected the initial data set by August 25, which included the 8-day delay.

The initial data set included details to cover the full shelf life of the product. As described below, Pilot Team 1 conducted further analysis and requested additional information from the retailer and processor in order to identify the single product lot, which traced back to two growers and a total of three ranch-field-sublot combinations. The traceback diagram (Figure 1) includes the traceback data for the full date range and highlights the traceback information related to the purchased product (as identified by the expert team based on the traceability data provided by the supply chain members).

Figure 1
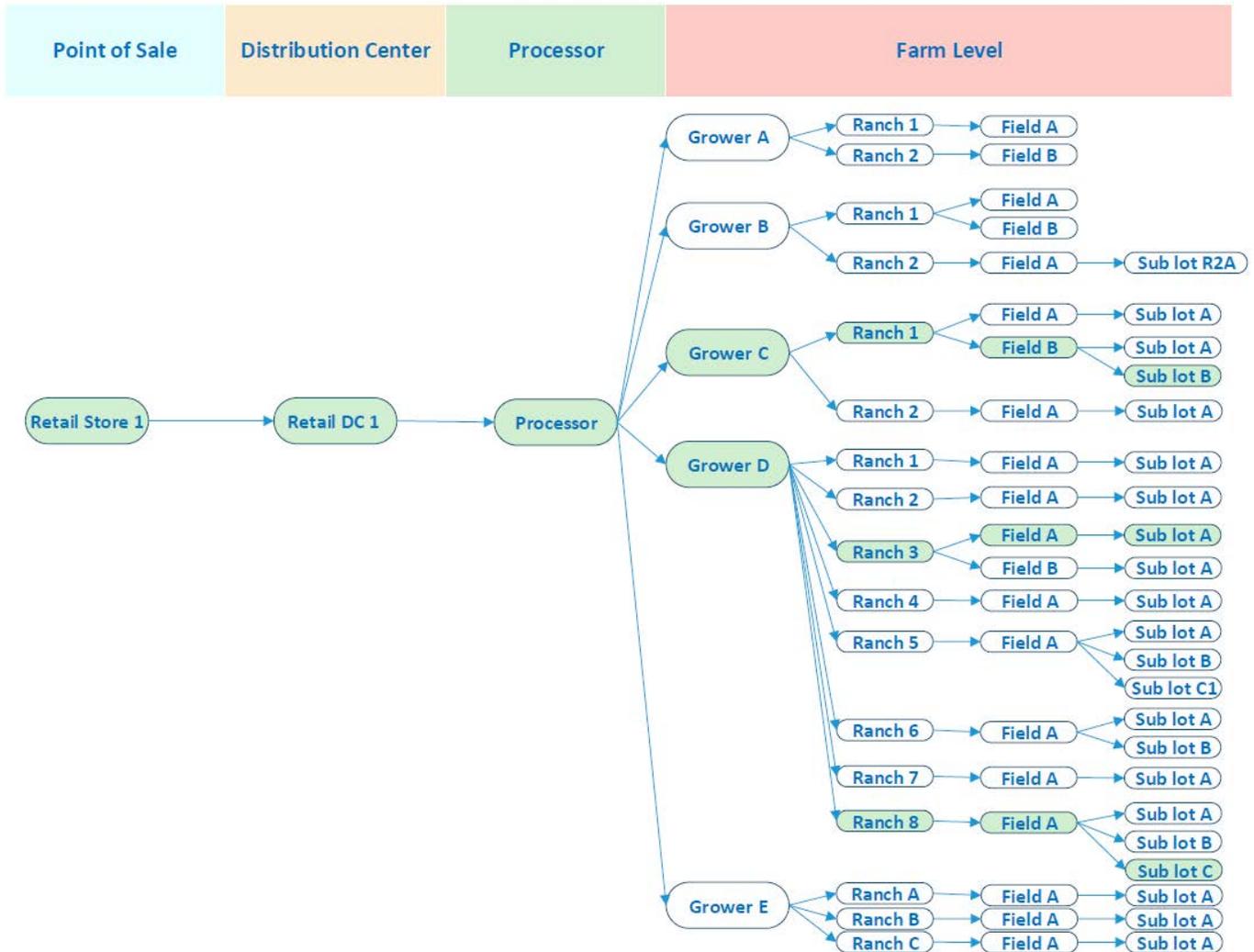
Within 24 hours of being contacted by the Pilot Team 1, the retailer was able to provide details of the purchase and shopper card information. The paperwork containing the information requested by Team 1 was provided within roughly 31 hours, but the retailer needed an additional 2 days to enter the necessary information into the template. In the interim, Team 1 remained in communication with the retailer, and provided additional education and explanation regarding the template. Each of the pilot participants provided comments on the template, and a key learning from the first pilot was that the template was not intuitive and required explanation. This is further discussed below.

There was an 8-day delay in the progression of Pilot 1 while waiting for the fresh-cut processor to sign the NDA. Clearly, companies responding to FDA requests will not need to sign an NDA, so this time is not counted against the total time to conduct the pilot. The fresh-cut processor was able to provide complete information, including details of the grower, ranch, field, sublot, harvest date, and in most cases harvest crews. The fresh-cut processor received a request for data related to the shipments received by the retailer on a Friday and returned the completed template the following Monday.

To be prudent, and to look at the "big picture" of production and movement through the supply chain, Pilot Team 1 initially requested data for the full shelf life of the product. In order to narrow the scope of possible finished product lots to those most likely purchased by the consumer, and therefore narrow the possible origin of the romaine purchased, Pilot Team 1 requested the following information from the fresh-cut processor:

- What is the shelf life of this product?
- Are there any shelf-life freshness date limitations you have for shipments to this customer/retailer (e.g. max/min number of days left on shipments)?
- Do you typically send mixed loads (with multiple lots?)
- Are there any other pieces of information you would use to try and isolate a single run? (e.g. time of day that you run this product vs. pickup times for this retailer?)

Using this information, the team then requested the following information from the retailer:

- Lot numbers received at the retail DC (captured as "best if used by" (BIUB) dates, manually written by DC staff on the Bill of Lading*)
- Daily sales data for that store (captured via universal product code (UPC) scan)
    - This product sells quickly and is restocked often
- Delivery times from the retail DC to the retail store
- Shelf stocking patterns
- Inventory reconciliation

since the purchase in June, the retailer's system had been updated to use barcode scanning to capture this information. In addition, the retailer requires suppliers to print lot numbers on the Bill of Lading

Pilot Team 1 used this information to eliminate or rule out products that would NOT have been in the store for purchases as well as products that would have likely and reasonably been sold already.   Using this reduced dataset Pilot Team 1 aligned the information against the format of the processors bag code identifiers and were able to produce a bag code down to the:

- BIUB
- Production code (Julian date, line, tube)
- Time stamp range
- Provenance labeling (Romaine from Salinas)

Identification of the finished produce lot code allowed Pilot Team 1 to identify the 2 possible growers and the ranches that were used to make the product (as highlighted in the traceback diagram). The detail extended beyond the correct identification of the finished product lot number; it included the line and the general timeframe of production that day.

4.1.2   Feedback from Pilot 1

Association partners captured feedback from each participant in the first pilot (the expert team members as well as supply chain participants) using discussion guide instruments. The comments below also include feedback offered verbally and by email throughout the course of the pilots.

Key comments from Pilot Team 1 members:

- Pilot Team 1 had many detailed comments on the template, but overall felt that they contained most of the right categories of information, but the nomenclature and some details needed revision. Overall, they supported improving this template, versus discarding it.
- Although the template had a user guide, it was not adequate to explain how the template was to be used
    - The template does not always align with industry terminology (depending on the supply chain node filling it out)
        - Pilot Team 1 suggested that different versions of the template should be created for different points in the supply chain
            - This could challenge the automated analysis of data
            - This assumes that all entities in that supply chain node (e.g., "distributors") are currently capturing the same data elements
    - Some fields, such as "PLU" are not relevant for a fresh-cut product. This created 'noise' in the template
    - Owing to the 'flat' format of the spreadsheet, which facilitates analysis and electronic sorting, the master data in the template becomes 'bulky' and quickly identifying the most useful data is visually challenging
    - Unit of measure needs to be separated from the quantity (for size)
    - Some fields assume a 1:1 correlation that might not exist. For example, the "shipments" tab has a field to indicate PLU as well as harvest date. Repacked bulk products may have a PLU, but a single shipment may correspond to multiple harvest dates. This would not be accommodated by the template in the current form
- Pilot Team 1 had personal connections at the retailer and fresh-cut processor but expressed concern that FDA and states would be less likely to have these contacts.
- Pilot Team 1 felt that the time it took the retailer to provide data, via the template, for the full shelf life of the product was relatively quick. Pilot Team 1 felt there was value in collecting the full data set and then narrowing down. They did not feel that asking the retailer for data for a narrower date range would have expedited the traceback.
    - The retailer reported that it took 3 hours to manually enter data into the template
- Pilot Team 1 was surprised that they received less detailed data from the retailer than expected (because the retailer is vertically integrated, and provided one data set to cover both their DC and store operations) and received more detailed information from the fresh-cut processor (who had insight into grower details).

Key comments from Pilot Team 1 supply chain participants (retailer and fresh-cut processor):
- The information provided by Pilot Team 1, and the questions they initially asked of the industry members, was rather generic and similar to the information FDA/ states typically request
- As Pilot Team 1 followed up with additional questions (aimed at identifying the finished product lot purchased by the consumer), the retailer began thinking about additional systems and tools at the retailer's disposal that could aid in the pilot:
    - Use of sales data regarding product turn
    - Use of BIUB date on the Bill of Lading (ideally this, the lot number, harvest date, or other unique identifier would be printed by the supplier)
    - Use of store video camera to view BIUB date (since it's on the front of the bag, and the register scans the UPC on the back)

- Although this approach was not able to be used, the retailer noted that as technology and systems improve, it could be a future consideration
- It was not clear to the retailer or fresh-cut processor that a different template file was needed for each location involved in the traceback. In other words, a file with shipping, receiving, and as applicable transformation should exist for each physical location where the product was present. For example, a retailer would have one file capturing receipt at the store, and a separate file capturing receipt at the DC as well as shipments to the store. This was unclear, and they attempted to capture all information within one file.
    o For the retailer, it was not clear that the store and distribution center should have different files
    o For the fresh-cut processor, who had information about the grower, it was not clear how one template could account for shipments from the grower to the fresh-cut processor (as receipts).
- The order in which information is requested on the template is not intuitive
- From the retailer side, several internal teams/ staff were involved in completing the exercise: Food safety/QA (standard practice rotation, shrink at retail; coordinating data requests across all functional areas; assembly of data submission), Supply chain/ logistics (DC's Bill of Lading, cases shipped – inventory), Operations (Video capability of purchase – review sell by date), Warehouse (Bill of Lading, product inventory team), Produce Category Management/Buyers (Sales and shrink data at store, vendor details, and contacts if necessary to coordinate internal calls), as well as IT and Marketing areas to confirm purchase data and description from the shopper card. Identifying and coordinating with the various entities can be time consuming and challenging.

4.1.3   Conclusions and key learnings from Pilot 1

- By understanding product movement in this supply chain, Pilot Team 1 successfully identified the lot number of the finished product purchased by the consumer and was able to further narrow it down to the timeframe and line of production.
- The "Best If Used By" date and lot number are both unique identifiers for the finished product UPC
- At the time of the purchase, the retail DC was not scanning barcodes on cases, but was manually capturing "Best If Used By" dates on the Bills of Lading that accompanied each shipment. This provided the necessary granularity of information for the DC.
- Although the retailer did not track shipments from their DC to retail stores by lot numbers or BIUB dates, the detailed information regarding purchases at the store level allowed Pilot Team 1 to confidently follow the finished product lot number to the store level on the purchase date
- The fresh-cut processor was able to provide detailed information on the growers, ranches, fields, sublots, harvest crews, and harvest dates for raw materials
- The fresh-cut processor was able to link the raw material lot numbers to the finished product lot numbers.
- The semi-continuous production of the finished product necessitated the use of multiple lots of raw material, corresponding to two different growers.
- The breadth and scope of the traceback diagram is most largely influenced by the initial date range for the inquiry (at the retail level)

- The traceback diagram is more focused and more accurate if the lot number of the finished (purchased) product is known, but in this case, still did not correspond to a single field.

4.2 Pilot 2 - Romaine product sold at an independent retailer that used a third-party distributor

4.2.1 Timeline and Results

Pilot Team 2 was challenged to trace a single purchase of Romaine made at an independent retailer (single store, serviced by a third-party distributor) on June 27 using only the consumer's shopper card number.

After receiving the FDA Romaine Traceback Pilot Mock Scenario detail on September 8, Pilot Team 2 used the information provided and contacted the retailer, which was the known point of purchase, for the affected consumer. Using the shopper card data (determined from the consumer name and phone number) and the estimated date of illness onset, a purchase of Romaine Lettuce made on June 27 was identified. The shopper card details included information on the brand of romaine purchased.

The retailer filled out the traceback template for receipts of the product in the selected date range of May 27 to June 27, as requested by Pilot Team 2. However, the retailer suggested that a narrower date range would more accurately focus in on the purchase, given the turn of the product at the store. The retailer maintains traceability based on purchase order receipts to determine on-hand inventory for the period being investigated. Based on the receiving data, it was determined that a single distribution facility supplied the romaine product over the timeframe of interest. This distributor was unknown to the pilot organizers, and an NDA needed to be executed. On September 10 it was determined that the distributor needed an NDA, which was sent on September 14 and returned on September 22, which introduced an artificial delay in the progress of Pilot 2.

A traceback request was made for the same date range from the distributor. Although the team received preliminary information from the brand owner (the source of romaine) that identified potential shipments to the distributor, the pilot team continued the formal steps to gather all the templates in a "one step back" fashion.

On September 29, Pilot Team 2 conducted further analysis and considered the known velocity of product movement for both the retailer and distribution facility and identified the two shipments as the most probable events that need further investigation, which traced back to two growers and a total of two ranch-field-sublot combinations. The team was successful as one was the correct lot.

The total duration for Pilot 2 was 21 days with 13 days lost waiting the distributor to return the signed NDA. A further 3 days was lost due to the retailer not being available. When contact was made with retailer, data was received within 2 hours. The distributor returned the template with the required information within 22 hours (8:21 am the next morning), which included the brand owner/grower information.

Traceback templates and data was requested and received from start to finish in 4 days. The initial data set included details to cover the full shelf life of the product. The distributor provided the completed traceback template with shipment data to the retailer and receipt data from the brand owner which included the potential ranches and fields.

The distributor maintains traceability records by purchase order information to determine possible on-hand inventory at point of shipment. This receipt data was validated by the brand owner/grower contacts.

The traceback diagrams (Figure 2) includes the traceback data and shows the traceback information related to the purchased product.

Figure 2
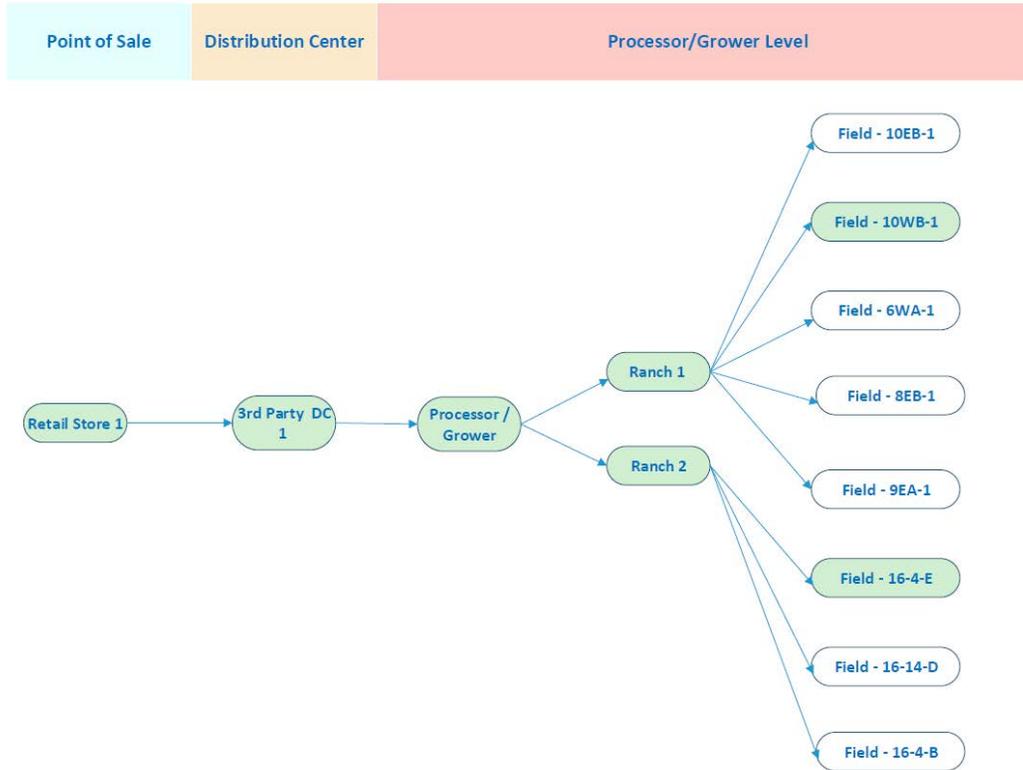
Each of the pilot participants provided comments on the template, and a key learning from the pilot was that the template was not intuitive and required explanation.

There was a 13-day delay in the progression of Pilot 2 while waiting for the distributor to sign the NDA. It was felt that this is an anomaly that the FDA would not experience. This time should not be counted against the total time to conduct the pilot.

The distributor was able to provide complete information for the total shelf life of the product (which was known by one of the expert panelists) with the exclusion of case GTIN and case Lot Number within 22 hours which included details of the brand owner (grower, ranch, field, sublot, best before dates, and harvest date). The distributor received a second request for data related to the:

- Inventory rotation practices
- Typical daily velocity
- Inventory on-hand by date
- Shipping protocol (i.e. FIFO, Code Date)
- Delivery frequency

This information was provided within 40 minutes of the request.
This additional information on the distributors business practices allowed Pilot Team 2to narrow their search to 2 specific lots.

Pilot Team 2 narrowed down the dataset for the 2 potential lots and were able to identify the:
- Best If Used By Date
- Production code
- Case GTIN
- Case LOT #
- Harvest Date
- Pack Date
- Ranch

4.2.2   Field Feedback from Pilot 2

Association partners captured feedback from each participant in the pilot (the expert team members as well as supply chain participants) using discussion guide instruments. The comments below also include feedback offered verbally and by email throughout the course of the pilots.

Key comments from Pilot Team 2 members:
- Pilot Team 2 felt that role specific templates would have assisted participants in filling out the template for the first time
- Generally, the correct data elements were requested on the template
- Overall, they supported improving this template, versus discarding it
- The Expert Team found the Shoppers Card information very useful
- The data points that were critical to finding the next node were:
  - PO numbers
  - Receipt numbers
  - Invoice and shipment dates (since lot number not tracked by distributor)
  - UPC
  - Product Identifiers
  - Velocity
  - Dwell time at each node
  - Date
  - Distributed By Name on package
- Data points received that were not used to evaluate the traceback were:
  - Size
  - Units per container
  - Receipt
    - PLU (because it was not loose product)
    - RAC or Fresh Cut
    - Packaging
    - BOL number
    - GLN's
    - Supplier Country Code

  - Shipments:
    - Case GTIN and Lot number not tracked
    - PLU (not loose product)
    - RAC or Fresh Cut
    - Harvest Date
    - Pack Date

- Inventory Data
- Code Date

- Although the template had a user guide, it was not adequate to explain how the template was to be used or it was not reviewed by the participants.
- Pilot Team 2 felt that the time it took the retailer and distributor to provide data, via the template, for the full shelf life of the product was relatively quick.
- Pilot Team 2 was surprised that they received the brand owner/grower information from the distributor. This reduced the time as they only had to validate the information with the brand owner.
- Pilot Team 2 felt that customers should share traceability information from their suppliers only with prior notification to party that owns the data, excluding information provided on the PTI label.
- Pilot Team 2 felt that data requests should be limited to only required information. Dates (Use By, Shipped, Received, Sold), Lot, Case Quantity, Purchase Order number, GTIN, and UPC (in absence of Lot Tracking, require inventory movement data which broadens results)

Key comments from Pilot 2 supply chain participants (retailer, distributor, and brand owner):
- The information provided by Pilot Team 2, and the questions they initially asked of the industry members, was rather generic and similar to the information FDA or states typically request
- The template asked for information that was not normally requested by FDA
- The retailer felt that the template was a little confusing as it had nonretail specific tabs and information and the retailer favored using a role specific template
- The distributor noted that the data request included attributes not automatically generated from their Warehouse Management System-generated mock recall template.
- The distributor felt that the initial email communication and template guidance were not 100% clear. The verbal conversation helped clarify the data request and assisted the Expert Team in understanding their operational procedures.
- Distributors comments on the template:
  - Shipment Tab
    - Commodity is repeated
    - Item description is used, not variety, commodity
    - Some items do not have a PLU
    - Do not capture and store case GTIN on receipt
    - Conventional and organic are in the description
    - RAC or Fresh Cut are included in description
    - Case type and packaging were not filled out
    - Lot/date are not normally stored on shipments
    - Columns W to AE are not required
    - AO to AR should be moved to left of spreadsheet (near C-M?)
    - AS to BF columns are redundant
    - Inventory position should be in receiving tab only
  - Receipt Tab
    - GTIN is available for receipts
    - Item description is used, not variety, commodity

- Some items do not have a PLU
- Do not capture and store harvest information. Was able to contact supplier to gather and input into template
- Conventional and organic are in the description
- RAC or Fresh Cut are included in description
- Lot/date are stored in receiving
- Columns AR through BD are repetitive
- Move supplier information toward left of spreadsheet
  - Why was customer GLN included?

- The distributor felt that the guidance document was semi useful
- The brand owner comments on the template:
  - Why the customer GLN was requested
  - A role specific template would be easier to use
  - Master data should not be repeated, e.g., PLU, item number
  - Took approximately 60 minutes to source data and fill out template
  - Was not given direction on which could/should be omitted vs which were mandatory.

4.2.3   Conclusions and key learnings from Pilot 2

- By understanding product movement in this supply chain, Pilot Team 2 was successful in identifying the 2 lot numbers of the finished product that could have been purchased by the consumer.
- The "Best If Used By" date and lot number are both unique identifiers for the finished product UPC
- If all points in the supply chain captured and stored the information on the PTI label, the record request and investigation would have been sped up.
- The brand owner was able to provide detailed information on the growers, ranches, fields, sublots, and harvest dates for raw materials
- A role specific template would be very helpful to all participants required to fill it out.

4.3   Pilot 3 - Private label salad (under USDA jurisdiction) from a national chain store

4.3.1   Timeline and Results

Pilot three, tracing a single purchase of a private label salad (that was under USDA jurisdiction) from a national chain store, began on October 6. On October 15, the team successfully included, as one of two possibilities, the finished product lot purchased by the customer.

Pilot Team 3 spoke with the retailer on October 7. A credit card, but not shopper card, was used. The retailer has a mechanism to rapidly respond to regulatory data requests, but it was

not used in the pilot as the request was not from government. However, the retailer gathered the credit card information and manually constructed for Pilot Team 3 the kind of information that would be provided to regulators. This included the exact purchase date and time, purchase location, and items purchased (including retailer item number which could theoretically be provided by more than one supplier, UPC, and a brief description which in this case identified the supplier). This information was provided to Team 3 on October 9.

Based on this information, the retailer identified (on October 9) 8 purchase orders on which the product was sold. Pilot Team 3 asked if additional information was available that could help narrow the range of POs, including ASN, sell or purchase by dates, shelf life information, store sales (POS) data, and/or on-hand inventory at the store. At the same time, Pilot Team 3 contacted the fresh-cut processor and was able to connect on October 12. Pilot Team 3 was able to analyze the information and submit their finished report/assessment on October 15.

Because the pilot was conducted more than 3 months after the purchase, the ASN data were no longer available based on the store's retention policy, but this has since changed. However, the retailer had specific shelf life requirements (days of shelf life that must remain when product is shipped to the DC, and days remaining when received at the store) which, when combined with the store inventory, allowed Pilot Team 3 to easily narrow the scope to two POs. As shown in Figure 4, the retail store was out of stock on this item for 7 days. The store began receiving shipments two days prior to the purchase of interest.

Although the product case bore a PTI label it was not scanned by either the processor or retailer. Because it was not scanned, Pilot Team 3 resorted to evaluating Purchase Order numbers and felt that the product purchased was most likely from the product received at the store on June 23 although the product received June 24 could also have been available (this was partly because the product received June 23 had a *later* Best If Used By date than product received June 24. Pilot Team 3 did not speak to store staff to determine if they look at use by dates, or if they restock based on "first-in/first-out" receipt of cases.). The retailer was able to provide the exact time that the store received the products on those POs.

Figure 4

POS Qty	Net Ship Qty	Daily
11	6	2020/06/01
9	6	2020/06/02
0	12	2020/06/03
1	0	2020/06/04
0	0	2020/06/05
0	0	2020/06/06
6	0	2020/06/07
0	6	2020/06/08
2	0	2020/06/09
4	0	2020/06/10
1	0	2020/06/11
1	6	2020/06/12
6	6	2020/06/13
3	0	2020/06/14
2	0	2020/06/15
0	0	2020/06/16
0	0	2020/06/17
0	0	2020/06/18
0	0	2020/06/19
0	0	2020/06/20
0	0	2020/06/21
0	0	2020/06/22
0	36	2020/06/23
6	6	2020/06/24
11	6	2020/06/25

The processor provided the raw material PO numbers and corresponding grower-ranch-lot identifiers (redacted by the processors) associated with the two finished product lots that were shipped on the two POs of interest, which traced back to six growers and a total of eight ranches (Figure 5). The processor was also able to provide to Team 3 photos of the labels from the finished products since the processor captures and retains these images as a matter of course.

Figure 5
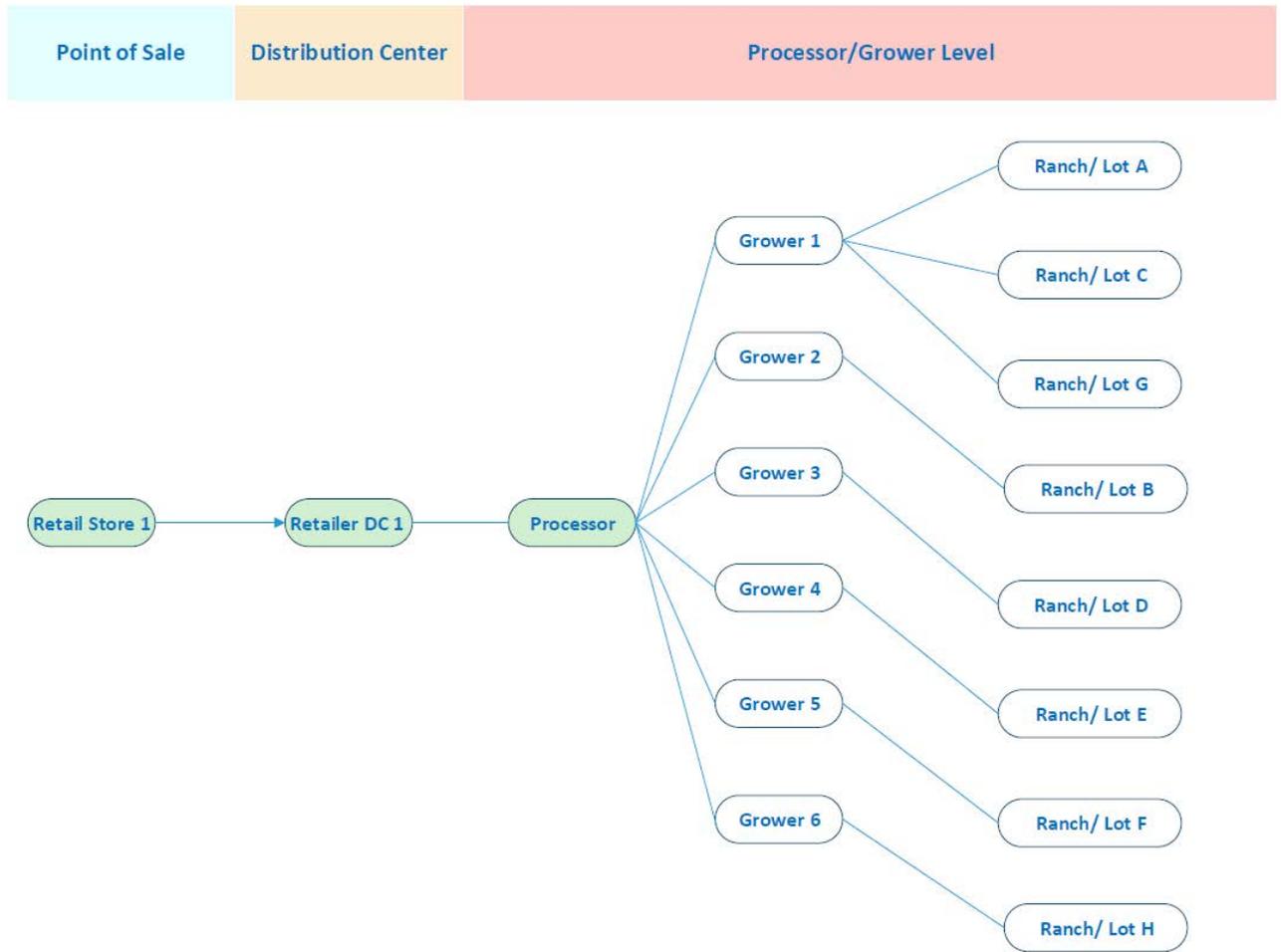
In this pilot, neither the retailer nor the individual from the fresh-cut processor who filled out the template had a great deal of familiarity with the template. Both of the pilot participants provided comments on the template, reinforcing that the template was not intuitive and required explanation. This is further discussed below.

4.3.2 Feedback from Pilot 3

Association partners captured feedback from each participant in the third pilot (the expert team members as well as supply chain participants) using discussion guide instruments. The comments below also include feedback offered verbally and by email throughout the course of the pilots.

Key comments from Pilot Team 3 members:

- Pilot Team 3 felt that they were able to traceback the product relatively easily because they "speak the same language as others in the produce sector" and knew to ask about how product moves through such matters as the supply chain and restocking practices.
- Having the specific purchase information associated with the credit card was critical.
- Because Pilot Team 3 are not regulators there was a longer response time from the retailer than would be seen from a regulatory request, but were still able to obtain equivalent detailed information related to the purchase, including the name of the supplier for the private label product.
- Pilot Team 3 had expected that the retailer would have lot code information related to the product. However, this had to be provided by the fresh-cut processor.
- Pilot Team 3 felt that the template seemed to take a "grower" perspective and was more difficult to use for later points in the supply chain.
- Because many fields in the template were not relevant to the retailer, or fresh-cut processor, this created confusion by those participants ("the template asks for information that they can't relate to, don't know, and don't care about). The retailer only had the PO, and this ultimately was sufficient to trace the product back.
- Pilot Team 3 suggested that the tabs of the spreadsheet be named by point in the supply chain, and that linking information auto populate from one tab to another. For example, if the retailer lists POs in their tab, this should appear in the processor tab, to cue the processor to enter information related to those POs.
- Although Pilot Team 3 relied on the grower-level information provided by the fresh-cut processor, one member of Pilot Team 3 felt that growers should be contacted to verify the information provided.

Key comments from Pilot 3 supply chain participants (retailer and fresh-cut processor):
- The retailer appreciated seeing the template to better understand the data expected and feels that it is more efficient than a broad ask. The retailer contrasted this with actual investigations where "the FDA simply tells us to provide everything we have".
- In real investigations the retailer typically refers FDA to their supplier. In the Pilot 3, the retailer received information from the supplier which provided the opportunity to checks, resulting in better data and better decisions. The retailer preferred the pilot approach.
    - The questions Pilot Team 3 asked the retailer about how product flows from the DC to the store and restocking practices at the store. This was viewed as an approach that FDA should adopt.
    - The retailer has historically been reluctant to share with regulators any information that they are not 100% certain of. However, they now are willing to brainstorm with FDA to help focus in on lot numbers and shipments of interest.
    - The retailer expressed concern that providing data more than "1 step back" could be a liability (if it is later found to be inaccurate) and feels that retailers who have this capability get singled out by FDA.
- The retailer is not convinced that, given the complexity of the supply chain, a single template can accommodate all situations.
- Because the main fresh-cut processor contact knew the Pilot Team 3 contact and they had worked together before, there may have been assumptions made about the understanding with respect to filling out the template. The processor had the regional staff person fill it out and did not provide much direction, resulting in the template

being used differently than the pilot team expected (e.g., the processor added fields and added information on the same sheet used by the retailer).

- It was not clear to the retailer or fresh-cut processor that a different template file was needed for each location involved in the traceback
  - For the retailer, it was not clear that the store and distribution center should have different files. The retailer reported that receipt to store was not included and would have been more difficult to obtain.
  - The fresh-cut processor used the retailer POs and added information on raw material lots that comprised the finished product lot numbers associated with those POs, and the grower information associated with the raw material lots.
- The retailer could automate fill in the template in the future, but noted it contained irrelevant data (e.g., commodity which is not applicable for a fresh-cut item, it lacked a field to include supplier contact info etc.)
  - It took the retailer approximately 1 hour to gather the information and an additional 30 minutes to fill out the template
  - The retailer did not review or use the user guide.
- The order in which information is requested on the template is not intuitive
  - The processor described it as "daunting"
- From the retailer side, several internal teams/ staff were involved in completing the exercise: Food safety/QA (vendor and operations teams), Technology (ASN compliance team, store operations technology team, etc.), Merchandising team and Recall team.
- From the fresh-cut processor side, the corporate food safety lead was Pilot Team 3's initial point of contact. However, the QA/food safety lead at the processing location took responsibility for filling out the spreadsheet. She consulted with the operations lead to ensure the production data were correct. The plant manager had oversight to make sure the exercise was completed.
  - While the processor worked to provide information in a timely manner they did not "drop everything" as they would have done had FDA requested information.
- The processor has an internal system from which they are able to determine the grower-ranch-lots based on the POs shipped to customers.
  - It took about 5 minutes to gather the information, and an hour to verify the data and enter it into the template
  - The template had too much information, most of which is not needed to trace back.

4.3.3   Conclusions and key learnings from Pilot 3

- Although the retailer did not track shipments from their DC to retail stores by scanning PTI labels the detailed information regarding purchases at the store level allowed Pilot Team 3 to identify two possible finished product lot numbers on the purchase date.
- By understanding sales data and product movement in this supply chain, particularly the time the product was out of stock, and rules regarding shelf life remaining on product, Pilot Team 3 successfully narrowed down the purchase to two possible lot numbers of the finished product.

- Because the retailer was very strict with respect to receiving product with certain shelf life, it allowed for inclusion/exclusion of shipments and could be a valuable tool to help investigators focus on product shipments of interest.
- The fresh-cut processor was able to provide detailed information on the growers, ranches, and raw material lots associated with the finished products
- The fresh-cut processor was able to link the raw material lot numbers to the finished product lot numbers.
- The semi-continuous production of the finished product necessitated the use of multiple lots of raw material. This corresponded to 6 different growers and 8 possible ranches between the two finished product lots.

5   Thematic Findings & Recommendations

The three supply chains tested in these pilots are by no means representative of the multitude of industry practices, supply chains configurations, and nuances associated with the industry. However, there were similarities between the three pilots that enabled the identification of themes. Although there is always room for improvement, the pilots showed that, despite criticisms of the ability to trace leafy greens through the supply chain, each pilot team was able to narrow down the lot code of the hypothetical "contaminated product" purchased by the consumer, which allowed for the identification of inputs into the finished product. In this regard, the association partners view the pilot as a success and encourage interested stakeholders to replicate and refine the approach to the pilots to reveal additional learnings.

At the outset of the pilots, the key objectives were to:
- Provide industry with better visibility into Coordinated Outbreak Response and Evaluation (CORE) traceability processes
- Examine utility of Produce Traceback Template, which was an outcome of the Romaine Task Force

Both objectives were accomplished, and the thematic findings are grouped into these topical areas.

1) Opportunities to leverage industry information to benefit the outbreak investigation process

Each of the three expert teams that conducted the tracebacks reported a better understanding of the traceback process and were occasionally surprised by which points in the supply chain retained different pieces of information. In all pilots, the teams augmented their requests for industry information and data beyond the scope of the Key Data Elements identified in the traceback template. It was these *other* data that were critical in identifying the finished product lot number associated with the purchase of interest. The types of information and the value they provided in the pilots are described below.

Shopper and credit card data: Investigators currently use shopper and credit card information, such as what was available in the pilots. The pilot teams found great value in these data and the purchase dates created "hard stops". In other words, product that was not yet available for purchase was easily determined to be outside the scope of the data request. There is an opportunity to standardize the way purchase information is requested by regulators so that

sufficient context is provided. On the industry side, there are opportunities to respond rapidly to these requests with enough specificity to identify the brand owner of the item of interest and begin to determine lot numbers or other identifying information.

Inventory, sales and other business intelligence
Once the purchase date was determined, each team needed to determine the date range for which to request records. Although two teams started with broad requests (based on assumed or reported product shelf life) and one time began more narrowly, ultimately each team based their final identification of the purchased lot code based on their understanding of product flow through the supply chain. Although the different industry participants captured or communicated slightly different information, each retailer had a detailed accounting of product sales at the store level. This paired with information on replenishment (based on shipments from a DC, receipts at a store, and/or restocking procedures) enabled each team to accurately determine the finished product lot code(s) available for purchase. Buyer requirements such as the number of days of shelf life that must remain also helped narrow the scope of the request and were used in the interpretation of product flow/movement. In each pilot, this information was gathered through additional correspondence with the retailer, supplier, and (as applicable) the distributor. The collaboration between the pilot teams and industry participants were critical to the success of each pilot team.

Each pilot team remarked on their approach to contacting the companies involved in the pilots. In many cases, they had personal relationships that could be leveraged, which is generally dissimilar from an outbreak investigation. In most cases, more than one individual from an industry participant contributed to the pilot. However, having a "point person" to coordinate the requests and communicate with the expert teams was critical. In several instances, key players were on vacation but were able to work internally to maintain progress and ensure information was provided to the expert teams in a timely manner. In some instances, one point in the supply chain reached directly to their supplier to gather information and identified the best point of contact by virtue of this process. This is something that the association partners have observed occurs in actual investigations. Again, clear communication of the situation and appropriate context needs to be provided so that the request for information is appropriately routed (e.g., to a recall/ crisis response/ food safety team).

Although not directly tested by the pilots, there was recognition that not all data are equally valuable and could potentially be "weighted" and evaluated through a probabilistic model. If records are requested for a broad date range, there are intuitively some shipments that are more likely to be of interest than others. Similarly, if some suppliers/growers are relatively small players in the marketplace, but are disproportionately represented in tracebacks, this seems amenable to further evaluation.

The pilots revealed an approach to triangulate key lot numbers through the process described above. An alternate approach could be to apply probabilistic modeling when it comes to specific data elements. Data elements could be weighed/assessed differently based on the supply chain knowledge, business intelligence and ultimately artificial intelligence. When there are many unknowns and variables (e.g., a date of purchase or exposure can't be confirmed,

necessitating evaluation of a wide date range), this can help assign probabilities to different legs of the traceback, to help investigators prioritize their resources.

2) Opportunities to Improve the Utility of the Produce Traceback Template

The template was a helpful tool in summarizing data that each supply chain participant may have had in disparate places (e.g., different software systems, different pieces of paperwork etc.). However, the detailed information (including both master data as well as transactional data) overwhelmed many of the industry participants, and the expert teams reported that only a narrow subset of the data were used to link product as it moved through the supply chain. Regardless of the edits and adjustments to the template, it's clear that education and training will be needed to encourage adoption and consistency in use.

Training & Education –

The industry experts and pilot participants were given a traceback template user guide. Unfortunately, the common feedback was that the user guide was not reviewed, but the taskforce certainly believes it is a MUST before using the template. Individuals typically did not review the user guide either because they lacked the time, or the document was too long and cumbersome to review. In some instances, the people completing the template might not have been the original contact, thus didn't not receive the user guide. These issues could have been addressed by providing a more streamlined and effective user guide within the template along with easy to understand visuals.

Areas of improvement and modifications-

The template was found to be cumbersome and daunting by most of the industry participants, particularly larger companies and non-retailers. Within the details of this report for each pilot there are comments on how to streamline the template including having specific supply chain partners only receive those sections of the template that relate to them. It was not clear to most users that a different file should be used for each location (e.g., one file to capture receipts at the store level; a file to capture information on receipts to and shipments from a DC; a file to capture raw material receipts, transformation, and finished product shipments from a processor, etc.).

The data fields could be better organized in the template based on the specific supply chain partner and their processes. Also, some additional parameters should be noted in the template including the "date of purchase" and the product movement/business intelligence previously described. This information, which directly relates to the scope of records requested, is the driving factor in determining the breadth and complexity of the traceback diagram.

Improved terminology should increase clarity and help a larger user audience better understand and complete the template in a more accurate and effective manner. Some terms mean different things to different supply chain partners, which results in confusion on what fields are applicable to that specific individual/business.

- "Transformation" was seen by some as too limiting and only focusing on a single ingredient, versus capturing the origin and use of multiple ingredients in multiple finished products
- "Commodity" field is not applicable for a processed product
- "Shipments" include data elements like harvest date, but a single shipment may correspond to multiple harvest dates

<u>Functionality of the template</u>

Automation of the template was desired by some expert team members to provide consistency and aid in establishing linkages to each data set. This includes drop-down menus and rules to standardize the way information is conveyed (e.g., standardizing state abbreviations, limiting the number of digits in fields such as for GTINs or UPCs)

Another desired feature was to automate linking of relevant data between different sheets, and different files. Currently, to the template is not set up to automate linking information within the various tabs of the spreadsheet, and to link spreadsheets to each other. Currently, there is not one data element, such as a lot number, that is carried through to the point of sale. Other data are available that establish links but the "linking" elements may need to be identified on a case by case basis. For example:

In pilot 1, the raw material lot number for the "grower" also appears in the "transformation" tab. It corresponds to a finished product "lot number" which also appears in the "shipments" from the processor.   The "shipments" also includes a PO number. The PO number also appears in the retailer's "receipts" tab   (at the distribution center).

NOTE: Additional information not amenable to a spreadsheet that was used to determine which "best if   used by" date (which has a 1:1 relationship with the finished product lot number), as captured by staff at   the DC, was available for purchase at the retail location based on sales volume and restocking patterns.

6   Appendix

A.1   User Guide- Template for Sharing Traceback Data with Regulators, deliberate draft for Leafy Green Pilot User Feedback 8-5-2020

1. Objectives

The goal of the template is to provide trace-back data to regulators. The template, in conjunction with this guide, supports that by:
- Provide guidance with respect to types and formats of data you may be asked to share with regulators/ investigators during a trace-back investigation
- Identify the Key Data Elements (KDEs) to be shared in a trace-back investigation
- Identify the basic Critical Tracking Events (CTE's) (the supply chain locations and actions) for which KDEs should be stored to support a trace-back investigation
- Provide a template for produce trading partners to complete at any point in the supply chain, to provide essential information to regulators during a trace-back investigation

2. Key Points
   Each entity/location in the supply chain should fill out their own template, focusing on the information applicable to the activities occurring at that location.
   - For example, a retail location will only provide information related to the store location selling the product in question. If that product was received from a distribution center, the distribution center would fill out its own version of the template.
   - Not all entities/locations will fill out all tabs of the template. Reference the table 5.1 below
   - Within each tab, there is:
     - Information that is required (e.g., names)
     - Information that is preferred (e.g., lot numbers) and
     - Information that only provides value if the preferred information is lacking (e.g., Bills of Lading numbers as a proxy for lot numbers).
     - NOTE: It's not necessary to fill out all data fields in the template, if you believe you've provided sufficient data to establish traceability links within your operation, and with your supply chain partners.

3. Template Overview
   There are 5 tabs on the PTI Traceback Template. This includes:
   a. Growing
   b. Shipments (Shipper)
   c. Transformation
   d. Receipts
   e. Attribute Definitions (reference sheet)

   The table below summarizes which entities may need to fill out the various tabs in the template. There may be exceptions, so please review the detailed information to better identify the tabs that may apply to you.

   These are listed in the order in which a traceback typically occurs, from the point of sale/ service, to the processor (if applicable), to the grower, inclusive of all points in between (e.g., recognizing that distribution may occur several times through the supply chain).

   Note: In some cases, a company may have activities in multiple roles, such as Grower, Packer, and Shipper. In these situations, the company should carry forward all the traceability information from their upstream activities, and utilize the relevant tabs, and as appropriate, fill out different spreadsheets.

Traceback Template Owners:

	Growing	Shipments	Transformation	Receipts
Point of Sale / Service	Unlikely	No	Only if in-store commingling occurred	Yes
Distribution Center	Unlikely	Yes	Only if repacking occurred	Yes
Processor / Re-packer	If possible	Yes	Yes	Yes
Shipper / Packer	Likely	Yes	No (unless mixing inputs)	Yes

Grower / Harvester	Yes	Yes	No	No

Point of Sale / Service
This refers to the location that sold or served the item to a consumer. This includes a retail establishment, restaurant, school, hospital, etc. This location should have details of the product received and served/offered for sale at the time in question.

In some instances, "retailers" may have their own distribution centers, own processing facilities, and even their own farms. For the purpose of the traceback template, refer to the *activity* being conducted, not the ownership.

Distribution Center
This entity represents a location where product was held or stored, generally with no manipulation of the product. In other words, the product was not touched, and the box was not opened, between receipt at the warehouse/distribution center, and the time that it was shipped to another location.

If repacking occurred *within lots* (such that there is no mixing of lots) there is no need to fill out a transformation tab. If more extensive repacking occurred, and different lots were mixed (e.g., between different suppliers, or between different lots/batches of the same supplier), then the transformation tab would need to capture the inputs associated with the repacked containers.

Processor / Re-packer
This represents entities that use different sources of raw materials to create a new product.

This could be a processed product where multiple types of ingredients are mixed into a new finished product (e.g., a salad blend with multiple components), or a single-ingredient product (e.g., shredded cabbage) where multiple lots of cabbage are combined in the finished product packaging.

This entity could also be a re-packer, where the product form is not altered (e.g., no chopping or slicing), but the "finished product" contains multiple inputs, such as repacking whole tomatoes from different lots into one case. The key point is that there are inputs, which are captured as "receipts", finished products, which are captured as "shipments". The "transformation" tab identifies the relationship between those inputs and resulting outputs. Depending on business relationships, the processor/re-packer may also know the farm-level information related to the raw materials used. In this case, they may be able to fill out some of the information on the "grow" tab.

Shipper / Packer
This point in the supply chain is receiving raw materials or raw agricultural commodities from the farm/orchard (the "growing" entity) and is shipping these products to customers. Because of the close relationship with the growing entity, shippers/packers may have visibility to the details indicated in the "Growing" tab in the template. It's important that these "inputs" link to the shipments. We are seeking feedback on whether this is most clearly communicated as a receipt and subsequent shipment, or a transformation.

Grower / Harvester
This is the origination point for a product. It can be a field, orchard, ranch, or other entity that creates the product. For purposes of this template, agricultural inputs are not captured. The grower is the terminal point of the traceback (the last entity revealed during an investigation) since it is the origin of the product.

A. Growing

This tab captures the point where the raw agricultural commodity begins its life. The corresponding location is the farm, field, orchard, etc. This tab should be filled out whether the product is field packed or harvested in bulk. During an outbreak investigation, this is often the location that investigators are trying to determine.

Examples of growing include

- Field packed romaine
- Apples harvested in bulk bins

B. Shipments (Shipper)

This is the actual shipment where traceable product is dispatched from a defined location to another defined location. Shipping events are typically followed by a subsequent Receiving event by another location. In some instances, a company could determine that shipping and receiving events should be recorded within their own company, such as when a product batch is transferred to another facility within their own company (i.e. store to store transfer). This should still be captured in two different spreadsheets: one per location.

More typically, this event (shipping) occurs when a traceable product is sent from one supply chain company (e.g. Grower/shipper) to another supply chain company (e.g. Processor).

Examples of shipments include:
- Grower to cooling shed
- Grower to processor
- Grower to Distributor
- DC to Store or restaurant
- Store-to-store transfer

C. Transformation

Transformation Events occur whenever a traceable product is transformed either by:
- Changing the nature of the product itself by mixing different sources of product, adding ingredients, cutting, or cooking; and/or
- By changing the nature of the product packaging, such as when a company places bulk product in consumer-sized bags for consumer self-service.

Transformation Input for documenting the identity of input products used and **Transformation Output** for documenting the identity of output of products from a transformation event.

- **Transformation Inputs:** One or more materials used to produce a traceable product that enters the supply chain.

  Examples of a transformation input event are when raw products or product ingredients from one or more suppliers or sources are processed, combined, or further processed by cutting, cooking, repackaging, etc. The objective is to capture the supplier, product ID, and production unit designation (e.g., batch/lot number, case serial number, pack date) of all ingredients used to create a traceable product.

- **Transformation Outputs:** Traceable product is packaged and labeled for entry into the supply chain. Examples of a transformation output event are when a new output product is placed into consumer item containers, inner packs, and/or cases and all package levels are marked to indicate supplier, product ID, and production unit designation.

  Note: Transformation events must share a common data element such as a production order that allows related input products to be associated with all corresponding output products to maintain internal traceability.

  Examples of transformations include:
  - Processor receives lettuce from single grower, shreds lettuce, puts it in bags, tracks inputs (from grower) and outputs (bags of shredded lettuce)
  - Processor mixes lettuces for a spring mix from several sources/growers. Tracks inputs (different growers, and different lettuces) and outputs (spring mix) with GTIN, Batch/Lot and date
  - Processor mixes leafy greens, carrots, tomatoes, cheese, and protein with packet of dressing for single serve consumer units.
  - Packer receives individual lots of red, yellow, and green bell peppers and puts one of each color into a single tray wrapped for sale to consumer as "stoplight" peppers with a new UPC. These consumer units are shipped in a case with a new GTIN compared to the original peppers.
  - DC has received romaine hearts in 25 lb. cases. They break those down into 5 lb. bags. Inputs are the 25 lb. cases; outputs are the cases of the 5 lb. bags.

D. Receipts

This is where traceable product is received at a defined location from another defined location. Receiving CTEs typically occur in response to an earlier Shipping event. Typically, this event occurs when a traceable product is received at a location after being transported between any two supply chain companies but could also include receipt at one physical location after shipment from another physical location under the same ownership.

Examples of receipts include
- Processor receives product from grower
- DC receives product from grower or processor
- Grocery store or restaurant receives product from DC
- Packing house receives fruits from multiple growers
- Store-to-Store transfer or DC to DC transfer

E. Attribute Definitions

This tab contains a list of all of the attributes found on the four previous worksheets. This includes the attribute definition, data type (if applicable), examples, GS1 descriptors (when applicable), and a guide showing attributes by event type – Growing, Shipments, Transformation and Receipts.
The Attribute Definitions tab also includes links to the *PMA Implementation Guide for Fresh Produce Data Standards and Synchronization* for further information and code lists.

About this Guidance Document

Guidelines are generally accepted, informally standardized techniques, methods, or processes that have proven themselves over time to accomplish given tasks. The idea is that with proper processes, checks and testing, a desired outcome can be delivered more effectively with fewer problems and unforeseen complications. In addition, guidelines can evolve to become better as improvements are discovered.

The Produce Traceability Initiative (PTI) is a voluntary U.S. produce initiative. The guidelines are the recommendations created and agreed to by all facets of the produce industry supply chain and PTI Leadership Council. Consent between trading partners may replace specific recommendations as long as the minimum traceability information requirements are met in good faith.

Key Data Elements (KDEs) and Critical Tracking Events (CTEs) are becoming industry terms as organizations across the food industry are looking to improve their track and trace processes. This guidance is provided as an additional resource to support industry members in responding to requests for trace-back data in the event of a market withdrawal or recall. This document should be used in conjunction with the PTI Traceback Template.

Revision History

Revision No.	Date of Change	Changed By	Summary of Change
R1.0	June XX 2020	Created by Technology WG	Initial Publication

A.2   Original Traceback template

Traceback_Templat
e_FINAL_v1.xlsx

A.3   Leafy Green Traceability Pilot: Interview Guide for Participant Volunteers V4

Supply Chain Participant Name/Company: To be completed by Industry Org Lead
Scenario No.: To be completed by Industry Org Lead

The purpose of this questionnaire is to collect pilot participant's feedback on the provided traceback KDE/CTE template that could be used to provide traceback information to a regulator upon request Key findings from the evaluation include:

- Ease of use
- How the template was filled out (manually or automatically)
- Time to complete it
- What areas or terms are confusing

Participant Information:
- Company:
- Title:

Overarching Questions:
- How similar or different was the pilot compared to mock recalls you ordinarily do?

- Were there any learnings or surprises from the pilot?

- The goal of the pilot was for the expert team to trace a single purchase back to its origin, as accurately and specifically as possible. Do you think there was any additional information that you could have provided the team to help them reach the goal?

Use of Produce Traceback Template:
1. Which department(s) provided data for the Produce Traceback Template? (*select all that apply*)

    a. Food safety/QA

    b. Supply chain/logistics

    c. Operations

    d. Warehouse

    e. Accounting

    f. Other:

2. Please the choose the response below that would describe the use of the Produce Traceback Template.

    a. Easy

    b. Medium

    c. Difficult, why?

3. Did you like the layout of the Produce Traceback Template? (Yes, no – why?)

4. Was the terminology in the template easy to understand? (Yes, no – why?)

5. Was the user guide for the template helpful? (Yes, no – why?)

6. How did you choose to populate the template?

    a. Automated

      b. Semi-automated

      c. Manual fashion

      d. If manual, do you think it would be possible to automate this process, given the current systems you currently use?

7. Approximately what amount of time did your organization utilize to populate the template?

8. What data requested in the template was the most difficult to obtain/populate?

9. In your professional opinion, do you think the Produce Traceback Template can be used to easily summarize requested traceback information?

      a. Yes

      b. Yes, with modifications

      c. Maybe

      d. No, why?

10. Is there any data you believe was not captured with this traceback template?

      a. Yes

      b. No, what is missing?

11. Do you have additional comments you would like to share with us about this experience?

A.4   Leafy Green Traceability Pilot: Interview Guide for Industry Leaders V4

Industry Leader: To be completed by Industry Org Lead

Scenario No.: To be completed by Industry Org Lead

The purpose of this questionnaire is to collect feedback from industry experts regarding the pilots, including the review of data in the traceback template, ease of using industry data to identify the product origin, and the opportunities for improvement to the traceback investigation process.

1. Overarching Questions

      a. Do you think that your team did a better job tracing back a purchase than FDA typically does? If so, why? If not, why not?

      b. How close did you get to identifying the exact product purchased, and how did you triangulate or deduce from a broader set of possible products?

         i. What information did you need to gather, and from what supply chain member, to help you in this process?

        ii. What information was not provided or not available that would have helped you narrow down the possibilities?

       c. What was the most surprising thing you learned throughout the pilot process?

       d. If you were to play the same role, and given the same scenario again, what would you have done differently?

2. Traceback Timing:

       a. Informing participant/securing NDA

       b. Ask/receipt of data request from participant(s)

       c. Time to evaluate data set and confirm the 'node' in the traceback

       d. If applicable, Overall time to complete all nodes to trace entirely

3. Data Availability:

       a. Was data available/submitted for each 'node' identified?

       b. Were there certain data points that were critical to finding the next node?

       c. Were there certain data points received that were not used to evaluate the traceback?

4. Conducting the Traceback:

       a. How far were you able to traceback the product (product owner/farm, field, row, etc.)?

       b. In your opinion, how difficult was it to trace the product back to the source(s)? (easy, little effort, difficult – why?)

       c. How helpful is credit card data in terms of speed/process to get consumer information?

       d. Was the date of purchase linked to the supplier name? (yes/no, comments)

       e. What information helped improve the speed or accuracy of the investigation?

5. Traceback Participation:

       a. If companies refused to participate, why?

       b. Who did you engage with at the store or corporate office for the shopper card info (their role and location)?

       c. What is the best way to identify the correct company contact? (facility registration, vs name provided by the customer, vs other source of information)

Questions on Traceback Recommendations:

6. The evaluation team should also consider how FDA processes could be adapted to obtain better quality information, more quickly. For example, what information should be requested of retailers and restaurants during the initial phase of the investigation when shopper card data is being collected?

7. What information should be requested (e.g., transactional data, vs Key Data Elements)? Should additional context be provided? If so, can this be done in a way that respects confidential information?

8. What points in the supply chain should provide information? Such as should growers be asked to provide data to substantiate information provided by their customers (e.g., processors)?

9. Should supply chain members be encouraged to share information about (gather information from) their suppliers, and/or their supplier's suppliers? Why/why not?

10. Under what conditions/arrangements should customers share traceability information from their suppliers?

A.5   Example of a Pilot Communication Log

Day 1 9/08/20 1:30 pm	Traceback launch. Pilot Team 2 received details on their traceback investigation
	Pilot Team 2 made initial voice mail contact with retailer
Day 1 3:00 pm	Pilot Team 2 member spoke to retailer to discuss data request
Day 1 4:55 pm	Retailer returned template with data via email
Day 3 11:28 am	Pilot Team 2 member made initial contact with distributor and determined a NDA was required.
Day 510:37 am	Retailer sent additional information on historical purchase information
Day 15 10:25 am	NDA received and Pilot Team 2 member sent template via email to distributor
Day 15 12:50 am	Pilot Team 2 member clarified with distributor details of the data request
Day 16 8:21 am	Distributor returned template with data via email
Day 16 2:58 pm	Distributor returned template with additional data via email
Day 18 9:25 am	Pilot Team 2 member sent email to distributor requesting clarifying information on dwell time, velocity, inventory and shipping practices
Day 18 10:17 am	Distributor responded to clarification questions

Day 22 9:00 am	Pilot Team 2 member made contact with brand owner to validate information provided by distributor
Day 22 2:00 pm	Pilot Team 2identified 2 lots that could have been purchased
	The Pilot Team obtained the date of individual purchase of the suspect item/ illness at the retailer which showed a purchase of June 24 from the shopper card information.
	The purchase was the only purchase with romaine lettuce or another item that may contain romaine lettuce.
	Pilot Team 2 requested distribution data (sales, inventory and velocity) from distributor.
	Contacted the processor and learned the processor harvested and shipped the same day.