Food Traceability Workshop

June 11 – July 1, 2021

Summary Report

Workshop Overview

The Food Traceability Workshop provided a platform for industry and government representatives to gather and educate each other on how product tracing occurs today and how it can be enhanced to meet the public health protection goals shared by both the industry and regulators in the future.

The workshop was organized with support from the American Bakers Association (ABA), American Frozen Food Institute (AFFI), Consumer Brands Association (CBA), The Food Industry Association (FMI), Institute of Food Technologists (IFT), International Foodservice Distributors Association (IFDA), National Fisheries Institute (NFI), National Grocers Association (NGA), National Restaurant Association (NRA), Produce Marketing Association (PMA), United Fresh Produce Association, and other leading associations and companies. The workshop occurred in three sessions over the course of five days in June and July 2021.

Session 1: Understanding the Supply Chain; Lessons Learned from Initiatives

In Session 1, industry representatives provided a series of high-level presentations on how goods move through the supply chain to point of sale and how supply chain partners communicate. Presenters then shared findings and lessons learned from recent studies and pilots on food traceability.

Overview of Supply Chain Structure

Overview of the Foodservice Supply Chain Structure
Erica Waara, Gordon Food Service, and members of the International Foodservice Distributors Association's Food Safety Committee | *Presentation slides available here*

Erica Waara provided an overview of the foodservice supply chain structure, beginning with a snapshot of the foodservice distribution industry and the large volume of deliveries it handles. She articulated three unique characteristics of foodservice distributors that have implications for traceability: 1) they purchase the same or similar products from multiple suppliers; 2) they sometimes serve only as the distribution arm of a purchase arranged between the customer and supplier, which limits their control over the information shared; and 3) they manage thousands of products from thousands of suppliers, which creates immense complexity. Ms. Waara described how products typically flow through the foodservice supply chain; pallets of products are received from suppliers and shipped at the case level to customers. She then described the information that is transferred through the supply chain and how this information (i.e., reference records and linking identifiers) is used on an almost daily basis to trace products forward (e.g., for recalls) and backward (e.g., for outbreaks). Ms. Waara finished the presentation by commenting that the congressionally mandated, FDA funded, 2011 IFT report on Improving Product Tracing outlined that the reference records and linking identifiers currently used by foodservice distributors are effective when conducting tracing investigations throughout the supply chain.

Participants asked clarifying questions about the information and tools foodservice distributors use to move and trace products. It was noted that such distributors have the necessary information to determine whether a product was imported, but that entry numbers are not usually used in outbreak investigations. Discussants clarified that foodservice distributors typically store and move products on pallets with a single product per pallet, but each pallet may contain multiple lots, which creates complexity. Pallets are traced using a pallet ID number created and assigned by the distributor. The pallet ID and other information is attached to the pallet, often using a digital tag (e.g., a barcode). Information about a product often comes to foodservice distributors on paper records, which these distributors then manually input into a digital record. During an investigation, foodservice distributors have sufficient information to link products from the customer level to the supplier level and determine which products came from which supplier, even for products potentially sold under the same item code.

Food Distribution/Information to Retailer
Hilary Thesmar, The Food Industry Association | *Presentation slides available here*

Building on IFDA's presentation, Hilary Thesmar provided additional information about the supply chain structure and how food products are tracked, highlighting the retailer experience specifically. She began with a description of FMI, its members' presence in the marketplace, and the types of products retailers sell and at what volumes. She differentiated between self-distributing and wholesaler supplied retailers, and explained the variety of store configurations in retail, including traditional grocers (e.g., supermarkets) and non-traditional grocers (e.g., drugstores and e-commerce). Ms. Thesmar listed types of documents used to track food products, including purchase orders, Bills of Lading (BOL), and advance ship notices, noting that data management systems vary across the industry. Some are electronic, but paper records are still heavily used. Challenging the common perception that the supply chain is linear, Ms. Thesmar emphasized that the movement of products is often multi-directional and offered a variety of delivery models that add further complexity (e.g., direct store delivery, cross docking, and private brands). Despite this complexity, she noted that product recalls, from announcement through to notification of consumers, are regularly executed in a matter of hours.

Recall Process Overview
Kelly Stevens, General Mills

Using General Mills' procedures an example, Kelly Stevens described key elements of a manufacturer's recall process. She outlined four primary steps in the recall process: notification, investigation, tracing, and communication, and spoke to critical types and sources of information used during recalls. Notification of a potential issue with a product or ingredient can come from multiple sources, including directly from a supplier, notification of an internal failure, or from a consumer complaint. Once notified of a potential issue or suspect ingredient, the manufacturer launches an investigation to determine whether they source from the suspected supplier and whether they received the suspected lot. If the answer is yes, the manufacturer performs tracing to determine where the implicated lot is, how much has been received, and whether the implicated ingredient has been used in finished goods. If it has, they initiate a finished good trace to hold the implicated product in inventory. While doing this tracing, the manufacturer considers several key pieces of information, including its own data in both paper and electronic systems (e.g., supplier data, recipe management systems, inventory management systems), and then cross references that information with manufacturing considerations to understand where, when, and how the implicated ingredient was used. Ms. Stevens emphasized that communication is critical throughout this process to establish clear roles and verify information internally and to communicate findings externally.

Other key points included:

1) Traceability from manufacturing perspective is efficient and effective.
2) Lot code is key piece of information, but not the only data point that needs to be considered during an investigation.
3) A manufacturer's knowledge of its systems and supply chain is critical to an investigation.

Review Industry Initiatives, Pilot Projects, Studies

Traceability: History, Learnings & Themes
Bryan Hitchcock, Institute of Food Technologists

Bryan Hitchcock introduced IFT and the Global Food Traceability Center (GFTC), a center that provides tools, standards, guidance, education and marketing for food traceability. Mr. Hitchcock provided an overview of the product tracing pilots IFT and GFTC led from 2009-2012 under FDA's FSMA Sec. 204 task order, which studied product tracing practices for produce and processed foods and offered recommendations on technical aspects and cost considerations with the goal of improving the accuracy and speed of recalls. These pilots resulted in 10 recommendations (detailed in this 2012 report): 1) establish uniform recordkeeping requirements; 2) maintain critical tracking elements (CTEs) and key data elements (KDEs); 3) require industry "traceback response plans;" 4) support industry-led initiatives; 5) communicate needed information; 6) develop standardized, electronic reporting templates 7) accept CTEs and KDEs in summary form; 8) request more than one backup; 9) use technology to share and analyze data; and 10) coordinate with state and local counterparts and use industry experts as appropriate. The pilots also surfaced key challenges for traceability, some of which remain today, including: collecting batch/lot numbers through distribution to point of sale (though other activity IDs, like purchase order numbers, are used effectively as an alternative); lack of standardized case labeling practices; lack of standardized data syntax; limitations in global connectivity; and the need for further education on foundational traceability concepts across the supply chain. Since these pilots ended, IFT has continued to do a wide range of additional traceability pilots with individual companies and full supply chains and to develop interoperability solutions. Mr. Hitchcock highlighted some of the implementation tools IFT offers, including an open-source database of sample code and IT solutions for traceability available on GitHub and financial analysis tools. He concluded with an overview of key lessons from IFT's pilot work: 1) traceability definitions and core concepts remain relevant and necessary even as new technologies are deployed; 2) interoperability is critical; 3) cross-functional and cross-supply chain buy-in is important for new traceability solutions; and the 4) the expanding and changing global market underscores the importance of traceability.

In discussion, Mr. Hitchcock added that data governance, security, and privacy are key components of traceability systems and interoperability. There is a recognition that protecting business sensitive information is paramount while establishing appropriate access rights. He also noted a large portion of IFT's piloting, tool development, and educational programs are targeted at smaller scale suppliers who are particularly challenged by the huge volume of information being requested by customers in different formats and through different technologies.

Blockchain: Lessons Learned from NFI's Seafood Supply Chain Traceability Pilot
Margaret Malkoski, National Fisheries Institute | *Presentation slides available here*

Margaret Malkoski offered lessons learned from a seafood supply chain traceability pilot NFI began in 2018. Ms. Malkoski explained that in the seafood industry there is a high need to gather and track product data both for regulatory purposes and to meet customer demands. However, these data are collected

through many different systems making data management unwieldy and overwhelming. The goal of NFI's pilot was to examine whether and how data management for seafood supply chains could be simplified and enhanced using blockchain technology. They piloted the use of IBM's Food Trust blockchain to trace information for two products: mahi-mahi from small scale wild fisheries; and imported farmed shrimp. The pilots revealed several challenges with adopting a blockchain system for traceability, including the steep learning curve for supply chain experts to understand programming jargon; the high complexity of seafood supply chains which increased the time needed to make the data management system work and potential for entry errors; and high resource costs (e.g., for hardware, software as service, internet access, and scanning equipment). A key takeaway of the pilot was blockchain (at least at the time it was tested) could work well for simple supply chains with few products but was less suited to complex supply chains. The pilot work group identified several hurdles that need to be overcome for the technology to be more effective: increased standardization and interoperability of data systems so that digital records can be easily transferred; more user-friendly interface (to decrease data input time user errors); infrastructure improvements to increase internet/technology access, especially abroad; and the company resources allocated for implementation and training. However, in response to questions, she added that some seafood producers have partially adopted third-party blockchain solutions and others are working to develop their own internally.

Lessons from the Produce Traceability Initiative
Ed Treacy, Produce Marketing Association | *Presentation slides available here*

Ed Treacy shared lessons from the Produce Traceability Initiative (PTI). The produce industry launched PTI as a voluntary effort to improve traceability following the 2006 USA Spinach Crisis which revealed insufficiencies of the industry's traceability practices at the time. The goal of PTI was to make produce trace back and trace forward investigations quicker and more accurate. The initiative pushed adoption of lot level traceability using case/carton labels and the use of three key data elements – GTIN item number, lot number, and date using GS1 standards – throughout the industry. Mr. Treacy outlined aspects of PTI that worked well, including:

- Establishing an organizational structure that was industry-led, but which leveraged cooperation among associations, GS1's global engagement platforms, and active work groups that developed new guidance.
- Development of a Voice Pick Code, technology that helped facilitate data entry and gain retailer buy-in.
- Cooperation with FDA in the development of resources.
- Regular and multimodal communication, including webinars, conferences, a standalone website, case studies, and association engagement.

He also suggested ways in which the initiative could have been improved, including:

- Emphasizing the benefits of PTI beyond traceability to supply chain efficiencies, which would have strengthened buy-in from suppliers, retailers, and distributors.
- Using Advanced Shipment Notifications initially rather than creating a requirement unique to produce (the Hybrid Pallet Label) which was replaced by ASNs.
- Greater engagement of retailer and foodservice associations and coordination with supply chain efficiency efforts launched in those industries at similar times.
- Incorporating the date in the GS1-128 barcode on the PTI Label initially.
- Less customization of PTI labels required by buyers.
- Resisting the expectation that any system will achieve 100% accuracy.

Today, about 60-65% of all produce cases are labeled and the industry is working to push that number even higher. In discussion, Mr. Treacy noted other benefits of PTI's efforts, including companies using the standardized label to more easily track other information/process (e.g., automating payroll, product destination) and saving costs on labeling and packaging inventory. He added that the current cost of adding a PTI code to a carton is ~$.01 or less.

Leafy Greens Pilots
Jennifer McEntire, United Fresh Produce Association | *Presentation slides available here*

Jennifer McEntire reviewed lessons learned from the Leafy Green traceability pilot conducted in Summer-Fall 2020 and prompted by FDA's Leafy Greens Shiga toxin-producing *E. coli* (STEC) Action Plan. The goals of the pilot were to provide industry with better visibility of the agency's traceability challenges and help the Romaine Task Force refine their CTE/KDE template. Dr. McEntire described three pilots that all followed the "secret shopper" model, in which the pilot teams were tasked with identifying what product a consumer purchased (down to the lot level) and tracing it back to the grower, given a purchase location, date range, and credit card or shopper card information. These pilots were an opportunity to ask questions and collect data differently than might be done in an actual investigation, as well as sharpening the Romaine Task Force's new track back template which industry had not used before. In all three pilots, the pilot teams were able to identify what lot was purchased (down to 2 possibilities) and to trace it back to its (possible) origins, using existing data and paperwork. They found that the sales, inventory, and product rotation data were especially useful to hone in on the lot number purchased, so that the records requested during tracebacks could be more narrowly focused. With regard to the template being trialed, the pilots revealed some uncertainty with the terminology used and who should be completing which fields, suggesting that more guidance/training should accompany the roll out of such tools. There was a sense the template could be useful with further refinement, including honing in on which data elements are indeed "key," noting that the pilots were conducted before FDA's proposed traceability rule was issued. In response to questions, she added that the pilots underscored the value of leveraging industry expertise in the development of regulatory tools and methods. The full pilot summary report is available here.

Session 2: Lessons Learned and Case Studies

Session 2 featured a series of case studies and lessons learned from various traceability exercises. Presenters outlined the current traceability capabilities for a variety of higher risk ingredients and products, and the key data elements industry currently uses to facilitate speed and accuracy of tracing in foodborne outbreak situations.

Views on the Role of Enhanced Traceability

An Overview of Traceback Investigations and Three Case Studies of Recent Outbreaks of Escherichia coli O157:H7 Infections Linked to Romaine Lettuce
Kari Irvin, U.S. Food and Drug Administration | *Presentation slides available here*

CDR Kari Irvin presented key takeaways from a review FDA's Coordinated Outbreak Response and Evaluation (CORE) Network conducted of three *E. Coli* outbreak investigations (full report available here). CDR Irvin provided a high-level overview of the traceback process and methods the agency follows in coordination with other public health partners from the point of exposure:

- *Confirming the illness through testing and collecting food histories from affected person to identify commonalities.* These steps are typically initiated at the local/state health department level. Food history data is shared with CDC (and for multi-state outbreaks CDC may serve as the coordinating lead from there). Food history data is verified against consumer purchase data to determine whether there was a common food item and whether it is connected to a specific source/region.
- *Initiating an investigation.* This begins with identifying a commodity to trace and the location, date, and purchase frequency of that commodity. This consumer purchase data can streamline the process if it can be shared quickly.
- *Reviewing documents and data about how the suspected product moved through the supply chain.* Throughout the process, FDA asks firms along the supply chain to provide information on the shipment, storage and handling of the commodity, trying wherever possible to avoid questions about specific business practices. Firms typically provide a variety of record types, including purchase orders, invoices, and BOLs.
- *Analysis and conclusions.* The agency uses information from the firms to identify shipments of interest and to see what other conclusions can be drawn about the contamination event.

CDR Irvin then described the three outbreak events linked to Romaine lettuce FDA reviewed in its study – the Spring 2018 outbreak traced to Yuma, the Fall 2018 outbreak traced to Santa Maria, and the Fall 2019 outbreak traced to Salinas. She spoke to the unique aspects of each, including the type of retail setting in which the product reached consumers, the contamination source, the types of records used in the investigation. She then outlined some of the key challenges associated with the tracebacks studied:

- *Initiation of Traceback*: Tracebacks are reactive (cannot begin until people are sick) and rely on information voluntarily given from sick people which can delay the traceback process.
- *Product-identifying information*: Lot codes not being maintained throughout the supply chain and in consistent product descriptions.
- *Record-Keeping*: it is difficult to tease out usable information from a wide variety of records, especially when those are inaccurate, illegible, or missing key information.
- *Co-mingling*: Use of multiple suppliers for a production lot broadens the scope of an investigation.

CDR Irvin closed by pointing to opportunities for improvement going forward, including learning from more pilots and studies, FSMA 204, FDA's New Era for Smarter Food Safety initiative, modernizing methods and tools for traceability and tracebacks in both industry and government, and the opportunity to leverage cross-sector collaboration.

In response to questions, CDR Irvin explained that the study underscored the value of lot codes and other electronic records in getting "back to farm" quickly. In an example where lot code was maintained, FDA was able to track back to farm in 24 hours. When relying on locating and examining paper records that process can extend to two or three weeks. She reiterated the point, made by other participants, that a lot code, or any product identifier, is only as useful as the data fields it contains.

Role of enhanced recordkeeping and traceability
David Acheson, The Acheson Group | *Interview recording available here*

In an interview with Elizabeth Fawell, Dr. David Acheson, CEO of the Acheson Group and former Associate Commissioner for Foods at the FDA, shared his perspectives on the role of enhanced recordkeeping and

traceability. Using the 2008 tomato/pepper outbreak as an example, Dr. Acheson stressed the importance of getting reliable information to investigators as quickly as possible during an outbreak. As was the case in 2008, incomplete or inaccurate information can lead investigators down "rabbit holes" that delay their ability to curtail the public health impacts of an outbreak and/or have very negative health and economic consequences when the wrong product is implicated and a dangerous product left on the self. Dr. Acheson spoke to one of the primary challenges to getting reliable data – the time elapse between consumption and when the illness and possible outbreak is reported to the public health community. On average it can take 10-14 days before the illness is diagnosed and reported to public health officials, and another week or two before patient questioning reveals a potential starting point. He suggested ways this process might be accelerated even before a suspect commodity is identified, including faster diagnosis (e.g., not waiting to form a batch of isolates before doing genome sequencing) and investing more resources/staff in public health agencies doing patient interviews. He stressed that doing the epidemiology and identifying a suspect commodity (or at least narrowing to a few commodities) is necessarily before attempting to perform a product traceback, and it is not until then that industry records become critical.

Dr. Acheson then shared his perspective on the record keeping requirements under FSMA and where he saw gaps both in the requirements and in compliance with them. He noted that FSMA exempted the very bottom end (growers) and very top end (retailers) of the supply chain from certain record requirements by design that are important to accelerate tracking, but that those are now areas where he sees the most challenges, especially for produce. He added that the supply chain risk requirements under FSMA have led manufacturers and producers to better understand their supply chains and account for risks. With regard to record keeping, he suggested it would be ideal if there were some sort of uniform identifier that remained consistent throughout the supply chain, though noted that could take many different forms. He indicated the primary challenge with lot codes is there is no standard definition of a lot so no guarantee that it will provide all of the information necessary to perform a traceback. To be useful, a lot code must include the right data elements, such as ingredient lots, grow date, manufacture date, harvest date, site, and others. Of course, from an academic or regulatory perspective more information and more granular information is always better, but he stressed that asking industry to track more information must be balanced against the value of that information and cost of implementation. He felt regulators' strategy should be to simply hold industry responsible for being able to determine where products come from, and let industry determine how best to accomplish that. Lastly, he stressed that even with perfect record keeping there can be situations where no convergence occurs in a traceback, which he tied back to his initial point about the importance of quality epidemiology.

Case Studies

Seafood

Margaret Malkoski, NFI; Ben Schwartz, Harbor Seafood | *Presentation slides available here*

Margaret Malkoski with NFI and Ben Schwartz with Harbor Seafood presented an overview of a traceback case study using Harbor Seafood's and a distributor's records from 2019 on Mahi-Mahi imported from Sri Lanka harvested by small scale fishery in the context of a hypothetical Scombrotoxin fish poisoning outbreak. Ms. Malkoski reviewed the Mahi supply chain from harvest to restaurant and the different types of records (both paper and digital) created as the product moved through the chain. Mr. Schwartz then described how these records would be used in a traceback, beginning with the product label, which in Harbor Seafood's case contains distributed by information, the item number, and manufacturer code. Cross referencing the label and purchase receipts, the restaurant was able to identify the product's distributor. The foodservice distributor also had records of what other restaurants received a case from

the suspected order. With the product order and shipment order information, the foodservice distributor retrieved the Bill of Lading showing the receiving event of the 160 cases from Harbor Seafood. In this case, those 160 cases were part of a grand lot consisting of two separate location lots of the same item sold by Harbor Seafood. Using the manufacturer lot code and item number on the product label, Harbor Foods could determine the exact manufacturer lot numbers and the specific implicated product. Mr. Schwartz noted that while the location lot identifiers will change as product moves through the supply chain, the production and manufacturer codes do not and are carried through the system. This information is connected to the manufacturer, PO number, original lot number, and other information in Harbor Food's internal enterprise resource planning (ERP) system, which can be used to determine where else the implicated product was sold and support trace forward. Mr. Schwartz emphasized that in most cases Harbor Foods can complete this traceback process very quickly; in this example Harbor Seafood was able to pull and cross-reference the information in 30-40 minutes. He then described the various types of records that are kept and exchanged (in electronic and paper form) as a product moves through the supply chain (e.g., from catch certificates to landing reports at the point of harvest, to production reports, to transfers between cold storage facilities), and the primary identifiers that are used to facilitate tracking: PO number, container number, and seal number. Mr. Schwartz also reviewed the responsibilities Harbor Foods assumes as an importer (e.g., maintaining copies of HACCP food safety plans for all manufacturers, annual records of the HACCP Certificates of Guarantee, and annual records of all 3rd party food safety and quality certifications). He stressed that because of the documentation they are required to maintain, the importer of record can be a key player in tracebacks. In conclusion, Ms. Malkoski and Mr. Schwartz affirmed that full traceback ability exists in the seafood supply chain.

Soft Cheese: Retailer Role

Hilary Thesmar, FMI; Darren Shadduck, Schnucks Markets | *Presentation slides available here*

Darren Shadduck with Schnucks Markets provided perspectives on the retailer's role in traceback investigations, drawing from a soft cheese recall case study Schnucks conducted. He began by emphasizing that retailers do traceback exercises fairly routinely, and therefore should be involved in investigations when they occur. Retailers often have information that help investigators make critical connections early on. In the case example, Schnucks assumed that blue cheese was the implicated commodity and used its inventory system to develop a list of all blue cheese products it sells. Schnucks' warehouse/distribution center was able to determine that they have had only one of those products in stock in the last year (because of COVID). Schnucks used that products' UPCs to simulate a recall. Mr. Shadduck noted that Schnucks (and most retailers) can issue a POS stop sale which blocks the entire UPC from being scanned, if necessary. Mr. Shadduck showed examples of the product inventory database and warehouse reports Schnucks uses and the types of information they include. In this case example, using the item code and PO number Schnucks was able to determine the expiration date of the suspected product (lot information), when products from the suspected lot were shipped to stores, and which stores received the product. Mr. Shadduck described how Schnucks manages its inventory (using a management application) and the types of information kept in that system, including PO number, lot code (for fresh and refrigerated items), vendor name and contact info, UPC, Schnucks related item number, receipt date, and expiration date. He closed by reinforcing the point that with key product information, including UPC and lot code/expiration date, retailers can trace backwards to the primary supplier and forwards to each store that received product. And, with the right questions from investigators, retailers are able to provide accurate and timely information which can speed up and facilitate an investigation.

Soft Cheese: Manufacturer Role
Marina Morero, Land O' Lakes | *Presentation slides available here*

Building on the prior presentation, Marina Morero with Land O' Lakes described a manufacturer's role in traceback investigations. First, she described the different ways an investigation can be initiated, including notification from regulatory agencies, suppliers, consumers, or customers. To then initiate the investigation, manufacturers focus on three key pieces of information: product name (UPC code), lot number, and the nature of the issue. Ms. Morero explained how product information is created and flows through Land O'Lakes' work system as a product is manufactured: 1) production planner creates a daily work order and a lot number is assigned to the work order; 2) at the warehouse where raw materials are staged an electronic application is used to enter ingredient and packaging information in the ERP; 3) on the production floor the operation issues the raw materials in the work order to complete production – the ingredients' lot number and quantity used in finished products are recorded, and pallets of finished products are scanned into inventory and pallet labels are printed; 4) the product undergoes quality assurance testing at the lot level and once approved is sent to a warehouse; and 5) warehouse personnel look for orders ready to ship and create a pick request. All documents generated during picking and shipping, the certificate of analysis, BOL, and invoice, are connected to the lot code and saved in electronic records. However, Ms. Morero noted that while this system is electronic, the majority of the data points captured at receiving are entered manually, and all the in-process manufacturing records are stored in parallel systems using manual records (spreadsheets or paper). The need to reconcile and/or verify their electronic records with external paper records can add time to traces. She noted that Land O'Lakes is sometimes challenged to obtain all the data required for its supply chain program because they are a relatively small purchaser of many of their ingredients. Nonetheless, if provided a lot code for a specific product number, the company can effectively and efficiently respond to recalls and trace products backward and forward through the supply chain.

Traceability in Restaurant Scenario: Pico de Gallo Case Example
Patrick Guzzle, NRA; Peter Goodwin, Bardenay Restaurant; Aaron Stepp, Charlie's Produce | *Presentation slides available here*

Using a mock scenario in which pico de gallo at a Bardenay Restaurant was suspected of making customers sick, Patrick Guzzle of NRA, Peter Goodwin of Bardenay Restaurant, and Aaron Stepp of Charlie's Produce demonstrated how a field investigator works with a restaurant and produce supplier during an investigation. They simulated the types of information an investigator would seek from the restaurant, including how often the suspected food is made and how is it served and the ingredients it contains and who supplies them. Mr. Goodwin provided examples of the invoice(s) for the suspected ingredients (in this scenario tomatoes and cilantro) Bardenay would provide in response to connect the investigator with the supplier, in this case Charlie's Produce. Mr. Stepp explained that using the invoice number and date, Charlie's Produce could determine the pick lot and pallet from which Bardenay's purchase was filled, and then pull the PO number and date it was received from the pallet tag. (He added that the pallet tag is also used and facilitates their first in, first out order fulfillment procedure.) Cross-referencing the PO with BOLs, Charlie's Produce could determine the grower of the produce in question. Mr. Stepp also explained how product information is entered and managed in Charlie's Produce's internal inventory tracking system, including how items are coded and tracked when full cases are "broken" into partial units. He noted that this system is maintained using a combination of automated and manual data entry. In Bardenay Restaurant's case all invoices are digitized and attached to their receiving record. Both Mr. Goodwin and Mr. Stepp estimated that locating the records necessary for a track back takes no longer than an hour. The presenters clarified that while the scenario they presented reflected tracking practices commonly used by restaurants, it is hard to say that any one approach is "typical" of the industry because of the wide variety of formats, sizes, and circumstances.

Product Trace Demonstration: Power Bowl Trace Case Study
Shawn Fear, ConAgra

Shawn Fear and other Conagra team members shared a product trace demonstration on a raw material used in a Conagra Brands Healthy Choice Green Goddess Power Bowl. Mr. Fear described how ingredients and products flow into and out of ConAgra, the records that are kept and created during this process, and the systems it uses to manage this information. ConAgra uses Oracle software to manage supply chain risk management (SCRM) data, including ingredient specifications and Certificate of Analysis (CoA) requirements, supplier contact information, and finished product recipes. As ConAgra receives ingredients, all associated paperwork (BOL, CoA, packing slips) and other ingredient information is manually entered into SAP software. From there, SAP is used to manage CoA, track materials receipt and usage, track finished product orders and movement, and finished product shipment information. ConAgra assigns a unique lot code to all semi-finished and finished products and pallets of finished products are assigned an LPN, all stored in SAP. ConAgra also used Every Angle software to quick fetch and organize data from SAP.

When a potential contaminant is identified ConAgra will conduct both a trace forward to determine where implicated finished products are located and a track back to understand if this material is present at other facilities or if other SKUs are impacted. For trace backs, ConAgra determines: 1) which ingredients were used in the product; 2) which lot of leafy greens were used to make the lot code(s) of implicated finished meal; and 3) who the supplier is and which of the supplier's facilities produced the lot. All of these steps can be done by cross-referencing data in the SAP system. The supplier is then asked to provide back to field data. This step often involves cross-referencing ConAgra's digitized records with paper records kept by the supplier. To trace forward, ConAgra determines: 1) where the lot was shipped from the plant using the pallet LPN sticker which contains the SAP lot code, the date of manufacture, and the plant identifier; and 2) where the product went after it left. In summary, ConAgra believes the use of electronic records provides efficient and effective one up and one down traceability for the organization. Additionally, Conagra is actively working to further digitalize record keeping efforts while exploring trace capabilities beyond 1 up and 1 down.

Trace Case Study: Peanut Butter Containing Manufactured Food
Cliona Murphy, Sarah Gooding & Rebecca Ferrer, PepsiCo | *Presentation slides available here*

PepsiCo's Cliona Murphy, Rebecca Ferrer, and Sarah Gooding demonstrated how PepsiCo conducts trace activities for a single product at a single facility (its Danville plant), using a Quaker Chewy Peanut Butter Granola Bar as a case example. Ms. Ferrer described the codes PepsiCo uses to track materials and how they are represented at different phases of the production and packaging process and the software systems used to host ingredient and product data. Incoming ingredients are tagged with an internal material tracking number. Consumer salable units are printed with the location, date and time of manufacture, and similar information is printed on the consumer salable carton and retail shipping case. The product code, location and date of manufacture are captured on LPNs on pallets. At all steps information is listed in both human readable and machine readable (coded) formats. Ms. Ferrer then described the operations flow of manufacturing and shipping a PepsiCo product, and the different people processes and data/systems processes used to track materials. She highlighted that in Pepsi's system the lot code assigned products at the time of product is key to connecting trace forward activities (from finished goods warehouse to distribution center to customer) and trace back activities (from receiving warehouse to receiving to materials specification).

Ms. Gooding then described two hypothetical scenarios in which epidemiological evidence suggests that people may be getting sick from peanut butter granola bars. In the first scenario a lot number is provided. Ms. Gooding explained how the Danville facility would be able to trace the suspected ingredient back from production to supplier. With the lot number, the plant can determine which ingredients were used in the product and determine which lot of the peanut butter ingredient was used to make the lot of implicated granola bars, using a Material Usage History Report generated by its material usage (MARS) system. The plant could then determine the supplier of the lot/ingredient in question and which of the supplier's facilities produced the lot/ingredient in question by cross referencing MARS data with the Unloading Tracking (ULT) system used at the receiving warehouse, which contains the supplier's name, supplier site address, and lot number of the ingredient pulled from the BOL. She noted that, during receiving, ULT information is manually entered into the MARS system by an operator and there is quality control business activity to verify data corresponds across systems. To trace forward, the plant can determine whether and where the lot was shipped from the plant after product has been palletized and warehoused. The plant's Warehouse Management system can produce a shipment history report that links the product lot code and the pallet license plate number with any purchase order number and the distribution center. The plant can also determine where the product went after it left the distribution center using an SAP Resource Planning Track Trace Tool and entering the material number and lot code.

In a scenario in which the lot number is not known, Ms. Gooding explained that PepsiCo could narrow the lot search to trace one or more lot codes, if provided with other data such as: ingredient type, supplier name, date frame, and stores where purchased. The PepsiCo team closed highlighting five key points:

- The product lot code key data element is the basis for their trace activities – forward and back.
- Manufacturing sites leverage both people processes and data systems to ensure traceability is maintained throughout the operation's process flow.
- Facilities vary by which digital and paper-based systems are used in tracing.
- Under FSMA supplier verification rules, PepsiCo tracks each high-risk ingredient to the manufacturing site.
- In compliance with the Bioterrorism Act, the trace activity can be achieved within 24 hours. Information would be provided from different systems and paper records.

Overarching Reflections on Case Studies

Following this series of case studies, participants offered comments on the themes and learnings they took away from the examples presented. Key points of emphasis included:

- The food supply chain is varied and complex with different entities accounting for different product types, business contexts and challenges, legal requirements, customer interests, and other factors.
- As such, there are many approaches and systems being used among suppliers, manufacturers, distributors, and retailers to capture and track product information. These approaches combine software systems/data with employees' expertise and knowledge of business practices. These approaches also often utilize a mix of paper and electronic records.
- Because approaches and systems do vary, there is often need for a "translator" (someone familiar with the company-specific processes and reference codes) to make company data useful to an outside observer.
- Though there are many different approaches and systems, it does seem certain record types are associated with, or more often used by, certain entities and/or commodity groups.

- Most supply chain actors use some sort of internal identifying number (e.g., lot code, PO, LPN) to track a product from the inbound side to the outbound side of their "link" in the chain, though these may be different link to link.
- Data digitalization and standardization is a worthwhile pursuit, but highly complex, expensive, and time intensive as demonstrated by the seafood and produce examples. Some in industry are further along in this journey than others; some do not have the resources to begin. Additional pilots in this area would be valuable.
- All case study presenters affirmed that they can trace products back and forward. The practices and technology used may be different, but the capability was consistent. Therefore, it may be more prudent for regulators to set outcome expectations rather than prescriptive process requirements.
- The epidemiology is critical. If given the right information (e.g., correctly identified implicated product or ingredient) industry can identify where that product or ingredient came from, but starting with the wrong information leads to rabbit holes and loss of time.
- There is a need for cross-functional teams (within companies) and interrelated supply chain relationships (between supply chain partners) to conduct effective and efficient traces. Similarly, collaboration and knowledge exchange between industry and regulators can greatly enhance traceability – both in the context of an actual investigation and with regard to the systems/ expectations that are established.

Session 3: Where Do We Go From Here

In the workshop's third and final session, participants turned their focus to the future. They worked in small discussion groups to brainstorm simplified solutions for accurate, achievable, and improved traceability, drawing on the examples and insights shared in Sessions 1 and 2. Then, participants began discussing the role of technology in improving traceability and other issues affecting development and implementation of tech-enabled end-to-end traceability systems.

Break Out Session #1: Most valuable information, records, and events for tracing product(s) linked to outbreaks and/or for executing recalls

Participants responded to three discussion questions related to identifying the information most critical to product tracing. Participants worked in eight small discussion groups, and, while responses varied across groups, many commonalities also emerged. The following is a synthesis of the responses and themes reported from all eight groups.

What three data elements are most valuable for product tracing?

Themes:

- It is difficult to pinpoint which data elements are most valuable for product tracing generally, because different industries and product types have different needs. For example, lot codes are critical to manufacturers but less meaningful and less widely used further down the supply chain.
- As such, several groups suggested it is more important to ensure that each "link" in the supply chain utilizes some sort of linking identifier, a code/tool that connects where a(n) ingredient/ commodity/product came from to where it went, but that this identifier need not be the same business to business.

- If specific data elements are going to be prioritized and/or required, they should be clearly defined or standardized. Participants pointed to lot codes, in particular, as an example of a tool that can be highly valuable at certain points in the supply chain but that is not used or defined consistently within industry.

In the context of these themes, groups did elevate certain key data elements. These are listed below roughly in order of how many groups named them as among the most valuable for product tracing:

- Lot code. Participants stressed that a lot code is only as valuable as the data fields it contains. Many of the other data elements below are often included in a lot code, but not in all cases. Many felt lot codes should be standardized and more firms should adopt existing standards, such as GS1 batch number or lot number. Further, at certain points in the supply chain, it may be more practical and efficient to use alternative reference records and linking identifiers, such as a purchase order number or bill of lading.
- Product identifier/item number/name in a standardized format (e.g., Universal Product Codes (UPC), Global Trade Item Number (GTIN), FDA established names)
- Manufacturer/supplier information, including location, contact information, and production plant code (e.g., state code/federal code, GS1 Global Location Number (GLN))
- Manufacture date and time
- Product image or product description
- Purchase order number
- LPNs (i.e., pallet IDs)
- Quantity of commodity/product
- Expiration date

What data elements should be maintained vs. forwarded along the supply chain if the lot code is always maintained and forwarded?

Themes:

- Again, the information that should be maintained versus forwarded will vary from point to point along the supply chain and depend on the industry and business/confidentiality interests. Some participants suggested this should be left to each industry to define.
- Perhaps because of this, there was not a great deal of consistency across groups in terms of which data elements they thought should be maintained versus forwarded along the supply chain (i.e., some groups said an element should be forwarded while others said it should just be maintained or vice versa).
- Most groups indicated that more information should be maintained than forwarded. Lots of data and information may have value for internal analysis, but would not be valuable to others in the supply chain if forwarded. Most agreed that simplicity is essential and only a few key data elements should be forwarded to increase efficiency and utility.

Which critical tracking events are valuable for product tracing if a lot code is maintained/forwarded along the supply chain?

Themes:

- Participants generally thought companies should keep records of the tracking events in which they are involved (not those that occur before and after the product is in their control), and that it was less critical for tracking events to be forwarded along the supply chain.

There was largely agreement among groups on which critical tracking events are valuable for product tracing:

- Movement of goods/any events which involve a change in ownership within the supply chain. This includes:
    - Receiving information (procured from where?)
    - Shipping information (sent to where?)
    - Purchasing records
- Quality and transformation information (e.g., when a product is made, packed/repacked, combined, divided, consumed). Depending on the product, this may include internal processing and food safety and quality assurance records/procedures (e.g., the manufacturing process, cleaning schedule/routine, whether and when a kill step is applied).

Overarching themes from Break Out 1

In the report out and discussion following the first break, several high-level themes surfaced that cut across all three discussion questions and were reinforced by more than one group.

- One size does not fit all when it comes to traceability approaches and tools. Different players in the supply chain have different needs, means, and business interests, and therefore the most suitable traceability solution will vary across contexts. That said, industries can learn from each other. There is enormous value in sharing and leveraging lessons learned and creative solutions across all food industry stakeholders.
- There should be a focus on simple, pragmatic traceability solutions. Data simplicity equals speed and accuracy. Because internal data needs and systems vary greatly company to company, the focus should be on identifying those critical data elements that truly enable traceability and developing simple mechanisms/protocols for sharing those elements.
- Good communication and strong working relationships with suppliers is critical. Often the most important data element is knowing who within your supplier network has the information you need. A strong point of contact can both enable quick access to data and help interpret/ translate those data to support an investigation.
- While not one size fits all, efforts should be made to define/standardize those data elements that are widely used and shared across the supply chain (e.g., lot codes).

Break Out Session #2: The role of data requests from regulators and how to refine and improve

In the second break out, participants discussed potential ways to improve how regulators collect information during outbreaks. Again, commonalities and differences emerged across groups. The following captures key themes and ideas generated in response to each of three discussion questions.

What questions should be asked by investigators to get the information they need to trace product(s) potentially implicated in outbreaks?

Themes:

- The questions that are most appropriate/useful to an investigation will vary highly based on the situation and where the investigator is in the supply chain (this was reflected by the breadth of potential questions break out groups generated).

- Whatever the regulatory ask or need, participants expressed a desire for investigators to be as specific as possible and to operate transparently, including being as forthcoming as possible with the investigation's challenges or issues. This will help industry provide the information most likely to aid the investigation.
- In some cases, participants suggested it may be helpful to reverse the questioning (i.e., allow industry to ask questions to which investigators respond).

Suggested questions for investigators to ask to trace product(s) implicated in outbreaks:

- Information about the implicated product (e.g., product ID, lot code, sell by date, manufacturing site and date, product description, pictures, ingredients used)
- Information about the production and/or handling process (e.g., overview of the production process, product rotation, timeframe of production, delivery schedules, inventory management processes).
- Information about the supply chain:
    - Where do you get the ingredients for the implicated products, including contact information for each supplier)?
    - Do you always get it from the same source?
    - How frequently do you buy this product/ingredient?
    - When were the last 2-3 shipments of this product/ingredient?
    - Do you still have the product in inventory?
- Information about the customer/consumer:
    - How was food used and how long was the product with the consumer/end customer?
    - What else did s/he consume?
    - Do you know anything about the symptoms of or impact on the consumer (from consumer complaints, etc.)?
    - Do you have loyalty/ordering apps to potentially help identify other consumers?
- Information about what tracing steps the company has already taken, if any:
    - Had you already been notified of the problem and if so by whom?
    - Have you recently done a traceback?
    - Have you done a trace forward?
    - Have you started a recall of the product?
    - Have you destroyed product?

Is there a way to standardize such information requests? How? (e.g., use of decision trees)

Themes:

- It can be helpful to have a standardized format in which the agency expects information. However, there should be room for flexibility given the uniqueness of different events and sectors of industry. Format should not inhibit the exchange of useful information.
- The further investigators can narrow the scope of an investigation and the more specific they can be with requests, the more easily and quickly industry will be able to provide useful information. Health departments could use additional training on making and using information requests on the ground (which industry can help develop).
- Decision trees can be useful to help industry and investigators quickly understand what information is needed based on the nature of the event. Different decision trees are needed for different sectors of industry (e.g., food service, manufacturing, retail).

Suggested ways to standardize information requests:

- Investigators and companies should begin with basic context setting
    - What is the situation?
    - Why are they contacting you (recall, complaint, sampling assignment)?
    - What information are they trying to gather?
- Understand how a company approaches tracking and tracing and the systems they use.
- It would be helpful to define/standardize key terms, such as units of measure (e.g., cases, meals, pallets), lot code, product identifiers, and the terms used to refer to other supply chain actors. Before, or in lieu of, standardization, investigators should ensure they know how the company in question defines/uses key terms, recognizing this differs company to company.
- The agency could develop a central recall portal with simple, standard questions. This could be done drawing on examples of portals used in other countries (e.g., Australia, UK) or that have been piloted domestically in the past.

Because State and local partners are often the first to arrive at retail during outbreak investigations, what information do they need to have and share to obtain what they need to trace product(s) potentially implicated in outbreaks? How can FDA enhance its communications with state and local partners and industry? Are there areas where consistency across jurisdictions would be valuable?

Ideas for how FDA could enhance its communications with state and local partners and industry:

- Ensure all parties (state and local partners, industry) have all appropriate epidemiological information and context to be able to participate as full partners in an investigation. Ensure everyone understands the problem they are collectively trying to solve, rather than just asking for records.
- Hold annual mock outbreak and investigation events with suppliers, manufacturers, retailers, food service, and state and local partners.
- Ensure that state and local level authorities have adequate training and qualifications to engage and collaborate with FDA and other federal agencies. Perhaps allow industry and state and local partners to have access to FDA training protocols for investigations.
- Potentially take an incident command approach with investigations, which could facilitate sharing best practices as well as increase speed and accuracy of data sharing.
- Further leverage video conferencing among regulatory teams and industry partners to aid with investigations and other functions.

Areas where consistency across jurisdictions would be valuable:

- A standardized process for investigations that can be used by state and local health departments and FDA. Consistency of process, regardless of who is leading the investigation (state or FDA), facilitates quicker response and more coordinated action.
- Consistency with information requests and the format in which they are requested would allow industry to focus on value-added tasks. Sometimes FDA will ask for one set of information in one format and the state will ask for another, which slows industry's response to both. Perhaps FDA could share consignee lists with all states to help avoid redundant requests from each state.
- Develop a centralized recall portal (see idea in previous question).

Overarching themes from Break Out 2

In report outs, participants collectively emphasized two primary points related to enhancing the way regulators work together (across levels of jurisdiction) and with industry during investigations:

- Regulators should seek information and knowledge, rather than raw data. Given the diverse array of coding and data tracking systems illustrated in case examples, records themselves are often not as critical as the translation of those records to answer questions and/or solve problems.
- Multi-directional communication is crucial to effective, efficient investigations. Participants suggested that regulators and industry should, together, shift the culture of investigations away from the, at times, adversarial extraction of data to collaborative problem solving. This would foster better communication, more creative thinking, proactive volunteering of information, and quicker responses. Participants added that this begins with public-private collaboration on how investigative processes and tools are designed.

Approaches to the Use of Technology: Challenges of Data & Systems Standardization, Business Processes, and Communication

In the workshop's final call, participants examined the role of technology in improving traceability. Presenters shared a series of new tools being developed and piloted to solve traceability challenges, as well as some of the limitations of, and practical considerations for, adopting tech-enabled traceability systems.

Role of data standardization
Liz Sertl, GS1 US | *Presentation slides available here*
Liz Sertl provided an overview of GS1 US and how GS1 Standards can be used to enhance traceability. GS1 is a user-driven non-profit that develops supply chain standards used by 1.5 million companies around the world. Standards enhance traceability by enabling interoperability. They allow companies to identify, capture, and share data in the "same language" and in a way that is compatible with existing business applications. Ms. Sertl described three types GS1 standards relevant to food product tracing: 1) identification numbers, including GS1's Global Location Number (GLN), and Global Trade Item Number (GTIN); 2) data carriers, including bar codes and RFID tags; and 3) data exchange, including GS1 platforms for sharing master, transactional, and event data. She also noted that GS1 US routinely partners with industry on pilots; indeed, GS1 US participated in several of the pilots described in this workshop including the Produce Traceability Initiative and Leafy Green Pilot. Ms. Sertl encouraged any company interested in partnering with GS1 US on a pilot to contact her.

Systems standardization: Review of one potential tool - Blockchain
Natalie Dyenson, Dole Fresh | *Presentation slides available here*

Dole Fresh is in the process of adopting IBM's Food Trust (IFT) blockchain supply chain management solution. Natalie Dyenson shared why Dole chose to use blockchain and the benefits and lessons they have observed so far. Blockchain is a shared ledger technology that allows any permissioned participant in the business network to see the system of record. It allows all parties to agree to each transaction, to execute transactions electronically, and it ensures that each party has the appropriate visibility of sensitive data. Each participating company, which in Dole's case are companies in its supplier network, decides what product information to put on the blockchain and who gets to view it. Data provided by companies is processed by algorithms into cryptographic hashes so that all parties can see the information but in a way

that protects privacy. Ms. Dyenson explained Dole has found blockchain saves time both for transactions and trace back/forward processes. It has reduced cost largely by removing intermediary record keeping and verifying steps. It has also decreased the risk of fraud and data tampering and increased trust through shared record keeping. Currently, Dole is live on IFT with two customers and four retailers in its network. They have over 500 SKUs in the system and process 14,000 transactions daily. The company has committed to moving all of its products to blockchain by 2025. Finally, through a series of screenshots, Ms. Dyenson walked through the IFT system and trace functionality which, after entering a product ID number, date range, and lot code, can generate a full record of that products movements back to farm in a matter of seconds. Regarding cost, Ms. Dyenson explained IFT requires no fee to enter data only to extract them. This allows suppliers (or anyone uninterested in analyzing the data) to participate with little to no burden, while Dole pays a subscription fee to access data reports.

Systems standardization: Review of one potential tool - Smart Label
John Phillips, PepsiCo | *Presentation slides available here*

John Phillips provided an orientation to SmartLabel and the ways PepsiCo envisions it being a vehicle to communicate recall information. SmartLabel is an expandable digital platform where consumers can access a range of product information that would not otherwise fit on a physical label. SmartLabel is accessed through a QR code on the product packaging. Today in the U.S. as many as 89% of consumers are using their phones (and QR readers) to aid their in-store shopping experience – a trend that has accelerated during the pandemic. Sixty-nine brands and over 89,000 products are currently using SmartLabel to meet consumers' increasing demand for product information, including health and safety information, allergens, certifications and other product claims, brand and company information, and contact information. With industry and consumer adoption growing, PepsiCo and other companies are expanding SmartLabel's use cases to support recycling directions, promotions, regulatory compliance programs, and traceability among others. Mr. Phillips demonstrated how companies plan to use SmartLabel to support near real-time recall communications. The SmartLabel landing menu can be updated with a recall alert header, enabling companies to alert consumers of a recall even after the product has left the store shelf. SmartLabel could also house additional recall information and FAQs like which products are affected and where consumers can get more information. SmartLabel could also facilitate recall communications to and from manufacturers, retailers, and media. Mr. Phillips noted that over the next 5-7 years industry will increasingly shift from UPC barcodes to QR codes/two-dimensional matrices to facilitate both retail transactions and SmartLabel functions.

Advanced Technology Systems today
Greg Pritchard, Nestlé | *Presentation slides available here*

Greg Pritchard offered insights on how Nestlé approaches traceability today and offered perspectives on the traceability innovations it and other companies are exploring and the benefits and limitations they have observed. Mr. Pritchard noted the food and beverage industry is highly diverse and fragmented. Nestlé is the largest food and beverage company in the world, yet it and the twenty other largest companies only represent 20% of the global market, the majority of which is small and medium size companies. Nestlé aspires to true farm to fork traceability and has achieved it for some product lines, but in most cases has achieved one up, one down. Mr. Pritchard described Nestlé's supply chain preventive control and vendor management program, noting that the sheer volume of suppliers it manages across a wide range of legal jurisdictions complicates standardization of traceability systems. Mr. Pritchard briefly described the SAP ERP system Nestlé and its partners currently use, key data entry and generation points, and how this system can be used to perform traces, primarily leveraging vendor batch codes, material codes, and Nestlé batch codes.

In most cases this system can be used to complete a trace in minutes. However, Mr. Pritchard also spoke to some of its limitations, including poor or inconsistent data from vendors, working with contract manufacturers who do not have an interoperable data management system, and the time (2-3 years) and cost (millions of dollars) associated with integrating new acquisitions. Nestlé is currently working to standardize its internal data standards and extend them to supply chain automation and data collection systems, which will eventually enable a blockchain style approach. Nestlé has previously piloted blockchain tools, but thus far found them too complicated, costly, and inefficient to adopt wholescale. Mr. Pritchard closed by affirming Nestlé is committed to embracing new technologies to improve food safety and ensuring that they do so in collaboration with all of their partners. In terms of business case, he saw particular value in tools and technologies that simultaneously serve food safety other business functions, like sustainability, transparency, and consumer trust.

Practical Considerations for the Use of Traceability Technology

Data management challenges: use of paper records
Maureen English-Carroll, Post Holdings

Against the backdrop of the many systems, tools, and new technologies shared during the workshop, Maureen English-Carroll spoke to some of the persistent data management challenges the industry faces, especially small companies and those at the ends of the supply chain. Data, computer, and language fluency within the industry workforce remain key challenges, and one of the main reasons paper records are so widely used, especially at the grower level. Ms. English-Carroll asserted that fully digitized/tech-enabled traceability will be a major lift for most of the industry. She suggested an iterative approach, focusing on areas where introducing technology will add significant value, rather trying to implement end-to-end approaches all at once. She also noted the challenge during an investigation is not lack of data, but effectively extracting the data – asking the right question or for the right report – to answer the question at hand, and that in some cases a sea of data is actually a barrier. Lastly, she noted all companies have resources limitations and should always seek to maximize the impact of those resources, especially in the food safety space. Given current industry practices, she suggested more resources should be invested in integrating paper and electronic records, rather than eliminating paper or moving entirely to costly technologies.

Challenges for suppliers
Sean Leighton, Cargill

Sean Leighton with Cargill offered additional thoughts on the challenges companies face in adopting and implementing tech-enabled traceability solutions in a global context, focusing on three areas: technology limitations, resource prioritization, and people challenges. He said the primary technology challenge is not developing a quality tool – blockchain, ERPs, and digital tags can all be majorly effective – it is developing a tool suitable and interoperable across the supply chain given enormous variety of business sizes, interests, and cultures. He added it is particularly challenging to achieve global interoperability by pushing a propriety software, which is why Cargill is advocating for interoperable *and* open-source solutions. Regarding resource limitations, Mr. Leighton emphasized prioritization of high-impact, high-value food safety solutions, noting it is easy to get caught on (and funnel money into) complex but relatively low-return issues. He recommended tech-driven traceability investments focus on high-risk foods, supply chains that already lend themselves to digitization, and as the industry does move to digitization, honing in on a small number of KDEs to simplify the transition. Finally, the primary people challenge Mr. Leighton observed is a natural disinclination to share data and information when one does not fully understand how that information will be used, yet a

need to overcome that disposition to fully harness the potential of technology. Cargill partnered with Intel to build an open hyper ledger fabric anyone can use to develop blockchain driven traceability tools, and launched several pilots using this resource. All of them showed promise but all of them stalled at the data sharing step because companies were unwilling to share real data. If tech-enabled solutions are to truly take hold, he stressed a need to build comfort across the industry with data sharing and with technology reliance, and relatedly, to groom food safety leaders with the disposition and business acumen to embrace this shift.

Keep It Simple: **Keep it Simple to Facilitate Broad Application; Focus on a Performance Standard**
Courtney Bidney, General Mills

Courtney Bidney emphasized the need to keep the mandatory FSMA 204 traceability requirements simple, to allow for voluntary application to all foods if companies choose to do so. She recapped some of the workshop's key takeaways, including that industry traceability programs are designed around the premise that there is a known contaminated food, that modern supply chains are highly complex, and that supply chain actors are using a variety of data management systems, both paper and electronic. She stressed that having the right information and the right people, those with supply chain and system knowledge, are critical to tracing activities. She added that it is important to separate regulatory requirements for traceability from longer term aspirations for end to end tech enabled traceability for all foods. Because of the complexity of the global supply chain, simplicity and flexibility are key for adoption and implementation of any traceability system or program. She offered the following recommendations: 1) prioritize a few KDEs with a focus on linking lot code; 2) ensure the traceability requirements can be applied to paper or electronic records; and 3) consider all other existing traceability requirements, including one up and one back (under the Bioterrorism Act) and supply chain management programs (under FSMA). She mentioned opportunities to enhance traceability by growers, restaurants, and retail food establishments currently not subject to some of the traceability requirements mandated for food manufacturers and distributors. She emphasized support for linking "lot code" throughout the supply chain and stated that this, combined with an industry performance standard for providing data to FDA, would provide the agency with the information needed to quickly trace product, while minimizing the recordkeeping burden on industry and creating flexibility for companies to determine the best method for achieving the performance standard.

She stated that an industry performance standard for providing data to FDA during an outbreak investigation, will achieve the goals of 1) getting to the source of an outbreak more quickly so that product can be removed from the marketplace and illnesses avoided and 2) facilitating more timely root cause investigations. Ms. Bidney also emphasized the importance of increased communication and coordination among the FDA, industry, and other partners during an outbreak investigation – a simple call between the FDA and a company after it has provided data can be enormously helpful. She recommended all participants focus their traceability and food safety investments on those areas where critical gaps still exist, which she suggested are traceability enhancements for growers, restaurants, and retailers and linking lot codes. She stated that while improvements to epidemiological investigations are needed, this is outside the scope of enhanced industry traceability.

Closing Remarks – Articulating a Future Vision

As the workshop concluded, Elizabeth Fawell highlighted some of the key themes surfaced across all three sessions, and how they might be leveraged to improve food traceability going forward:

- The global food supply web is highly complex. Food traceability requirements and technology solutions must account for this complexity.

- Many different supply chain management, inventory management, and record-keeping systems are used across the industry, including a mix of paper and electronic systems and digital and manual data entry approaches.
- Pilot projects have revealed several challenges including: internet access; data standardization; use case; technology learning curves; and the need to focus on key pieces of information.
- The epidemiology is key. Most industry traceability systems are designed with the assumption that a suspect commodity/ingredient/product has already been identified. That said, industry can and should collaborate with public health officials to support epidemiologic investigations.
- Companies are effective at product tracing today, including through the use of paper records. Nearly all have one up/one back capability and many have supply chain visibility beyond that. It was also evident that although companies may understand their records, it can be hard for third-parties to understand that data. Therefore, many participants suggested FDA focus less on requesting and deciphering records during traceback investigations, and instead focus on asking questions and gathering information from industry.
- Simplicity of traceability information is important. Key data elements include the lot code, the product identifier, and the date. Additional information may be helpful at particular nodes in the supply chain to certain entities, but does not necessarily need to be passed forward in the supply chain in a standardized way. Some participants commented that forwarding information could make things more complex and cumbersome.
- Many new traceability-enhancing technologies are being developed and piloted. All have pros and cons and all have proven to be suitable for some businesses while unworkable for others. There is value in and need for more pilots and discussion about many unexplored issues such as security and privacy.
- Standardization and flexibility are both necessary. There is an opportunity to standardize key terms/tools (e.g., lot code) and processes (e.g., data requests), but the process of standardization must account for the diversity of approaches and needs in the industry. In addition, standardization will take time.
- Industry representatives welcome further cross-sector dialogue as FDA works to develop and rollout its New Era of Food Safety initiative.

Ms. Fawell and other members of the workshop Steering Committee thanked all participants for their contributions to this workshop and ongoing dedication to improving food safety.