Comprehensive REVIEWS in Food Science and Food Safety

A Guidance Document on the Best Practices in Food Traceability

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Abstract: Several regulatory agencies around the world are involved in rulemaking to improve the traceability of foods. Given the complexity of the global food system, guidance on improving traceability practices across the entire food industry is a challenge. A review of the current regulations and best practices indicates that "one back, one forward" is the minimum traceability requirement. There are also no uniform requirements across different food sectors, supply chains, or countries for collection of Critical Tracking Events (CTEs) and Key Data Elements (KDEs). There is a need for standardized and harmonized requirements across all food sectors compared with developing specialized rules and mandates, including exceptions, for specific foods. This document presents food traceability best practices guidance and it addresses the unknowns and gaps in understanding and the broad applicability of a CTE–KDE framework. It applies this framework to 6 food sectors as bakery, dairy, meat and poultry, processed foods, produce, and seafood. An analysis of similarities and differences across these sectors is conducted to determine broader applicability to other foods. Fifty-five experts from 11 countries were involved in developing this guidance. This guidance document is intended for regulatory agencies and the food industry. Regulators will find it useful in developing regulations and/or guidance applicable to most foods. Industry will find the minimum criteria that are necessary to manage a proper food traceability system, with the understanding that companies can choose to exceed the minimum level of criteria established. This guidance is intended to serve as a step toward consistent baseline requirements for food traceability.

Keywords: food traceability, food regulations, guidance, best practices

Introduction

Food traceability is a cornerstone of the increasingly complex, industrialized, and global food system. Food traceability is useful for producers and manufacturers to track items for supply-chain management purposes and for clients; and in the event of a recall, traceability is critical to protect consumer health, especially when large quantities of contaminated products are distributed across widespread markets. Food traceability is about more than recalls. Being able to ascertain the origin of products and their attributes from the farm through food processing and to retail and food service and into the home is growing in importance. Increasingly, public health concerns are demanding traceability. But economic competition, which will reward those who can more effectively and reliably track and trace product back and forth through each step of the chain, will drive it.

Food production is at an historical high, compounding the issues surrounding traceability. The top 20 agricultural products sold in the United States involve the production of 692 million metric tons of food (FAO 2012). The top 20 agricultural products globally involve the production of 6.76 billion metric tons of food (FAO 2012). This food is needed to sustain the estimated 7 billion people living today. However, it can also be a carrier for foodborne illnesses. In the United States alone, an estimated 48 million cases of foodborne illnesses occur each year and result in 3000 deaths and 128000 hospitalizations (CDC 2014a). According to the Centers for Disease Control and Prevention's (CDC) annual foodborne illness progress report, there has been no change in case rates attributed to *Escherichia coli* O157, *Listeria*, *Salmonella*, or *Yersinia* during the period of 2006 to 2008; a 75% increase in *Vibrio* cases and a 13% increase in *Campylobacter* cases (CDC 2014b).

Education, rapid analytical testing, advancing scientific methods, advances in regulatory oversight, and Hazard Analysis and Critical Control Points (HACCP) food safety management systems have all been vital to curbing outbreaks and reducing illness outbreaks, but foodborne illnesses till occur (as noted above). Effective and rapid traceability is a key to minimizing occurrence of foodborne illnesses. A coordinated and quickly responsive global traceability system is a crucial component of an integrated food supply chain that achieves the foodborne illness reduction goals we all desire. Several regulatory agencies around the world are actively involved in rulemaking to improve the traceability of foods (Europa 2011; FSANZ 2011; CFIA 2012; FDA 2014; MAFF n.d.).

Given the complexity of the global food system, the development of regulations and guidance to improve traceability practices across the entire food industry is a challenge. There is a need for standardized and harmonized requirements across all food sectors

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doi: 10.1111/1541-4337.12103

compared with developing specialized rules and mandates, including exceptions, for specific foods.

On the one hand, standardization would provide regulators the opportunity to resolve outbreak-related trace-back investigations emergency with much greater efficiency and effectiveness than possible today. On the other hand, industry stakeholders, however, need sufficient flexibility that allows them to adapt traceability requirements to specific foods and business operations. The challenge being faced today is the gap between regulatory requirements and the feasibility of industry implementation.

Several regulatory and industry initiatives have proposed frameworks for resolving this challenge. Most traceability initiatives led by the industry and industry associations for developing traceability guidance documents focus on their specific food-product categories (Bhatt and others 2012). Only a handful of organizations have evaluated traceability approaches that could be applicable across the entire food industry. The 2012 pilots conducted by the U.S. Food and Drug Administration (U.S. FDA) proposed such a framework, using the concept of Critical Tracking Events (CTEs) and Key Data Elements (KDEs) (Bhatt and others 2013). However, since the focus of these pilots was on 2 specific food-product categories (fresh tomatoes and processed foods), the applicability of the CTE/KDE framework to other food sectors has remained undetermined.

This document presents food traceability best practices guidance, and addresses the unknowns and gaps in understanding and broad applicability of a CTE–KDE framework. This document does so by first updating the original CTE-KDE framework, defined by the Institute of Food Technologists (IFT), to allow it to be more readily applicable across different food sectors (since the original study only focused on tomatoes and a processed food with peanuts, spices, and chicken) (Bhatt and others 2013). Then, it attempts to apply this updated framework to each of the following 6 food sectors: bakery, dairy, meat and poultry, processed foods, produce, and seafood. An analysis of similarities and differences in applying the updated framework across these 6 food sectors was conducted to determine applicability to other food categories/types.

The intended user of this document is national and international regulatory agencies. Regulators may find this material useful in developing regulations and/or guidance applicable to most foods. Industry-affiliated stakeholders will also find this guidance valuable. It is recognized that the food industry seeks the minimum criteria that are necessary to manage a proper food traceability system, with the understanding that companies can choose to exceed the minimum level of criteria established. Although this best practices guidance document is not a regulation, this document is intended to serve as a step toward consistent baseline requirements for food traceability.

Background

Food traceability system within a supply chain

Implementing a traceability system within a supply chain requires all parties involved to link the physical flow of products with the flow of information about them. Adopting uniform industry requirements for traceability processes ensures agreement about identification of the traceable items between parties. This supports transparency and continuity of information across the supply chain.

External traceability. All traceable items must be uniquely identified, and the information be shared between all affected distribution channel participants (Natl. Fisheries Inst. 2011). The identification of products for the purpose of traceability may include assignment of a:

- Unique product identification number; and
- Batch/lot number.

To maintain external traceability, traceable item identification numbers must be communicated to distribution channel participants on product labels and related paper or electronic business documents. This links the physical products with the information requirements necessary for traceability.

Internal traceability. Processes must be maintained within an organization to link identities of raw materials to those of the finished goods. When one material is combined with others, and processed, reconfigured, or repacked, the new product must have its own Unique Product Identifier. The linkage must be maintained between this new product and its original material inputs (such as batters, breading, seasonings, marinades, salt, packaging materials, and many other inputs) to maintain traceability. A label showing the Lot Number of the traceable input item should remain on the packaging until that entire traceable item is depleted. This principle applies even when the traceable item is part of a larger packaging hierarchy (such as cases, pallets, or shipment containers).

Internal and external traceability. Farm to fork traceability requires that the processes of internal and external traceability be effectively conducted. Each traceability partner should be able to identify the direct source and direct recipient of traceable items as they pertain to their process. The implication is not that every supply-chain participant knows all the data related to traceability, but rather show proof that relevant members/partners in the supply chain have done their jobs and that information can be accessed if needed. This requires application of the one-step-forward–one-step-back principle and, further, that distribution channel participants collect, record, store, and share minimum pieces of information for traceability, as described below.

To have an effective traceability system across the supply chain:

- Any item that needs to be traced forward or backward should be identified with a globally unique identifier.
- All food chain participants should implement both internal and external traceability practices.
- Implementation of internal traceability should ensure that the necessary linkages between material inputs and finished product outputs are maintained.

Important considerations for an effective food traceability system include:

- Trading partners (farm input suppliers, farms, harvest locations or vessels, suppliers, internal transactions within a company, customers, and 3rd-party carriers).
- Product and processing locations (any physical location such as a hatchery, cultivation site or pond, farm, vessel, dock, buying station, warehouse, packing line, storage facility, receiving dock, or a store).
- The products that a company uses or creates.
- The logistic units that a company receives or ships.
- Inbound and outbound shipments.
- Date and time metrics as appropriate.

Essential information must be collected, recorded, and shared to ensure at least one-step-forward—one-step-back traceability. This

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best practice is applicable to companies of any size, degree of sophistication, or location.

Identification is critical to a successful traceability program. Usually this is accomplished by labels and any number of technologies can be employed for labeling, including simple handwritten labels and more sophisticated radio frequency identification (RFID)-based technologies. However, barcoding remains the most common industry best practice for packaging hierarchies for shipping logistical units (such as cases, pallets, shipment containers, consumer items, and others). The barcode should at least contain the product identification number.

Businesses are encouraged to adopt electronic messaging protocols to facilitate the exchange of essential business information using unit identification as a connector between goods and information flow. Businesses are also encouraged to adopt standardized interfaces (protocols for two-way communication) for sharing essential traceability event information within a network, thereby allowing reduction of the substantial size of data transmission along the supply chain.

Traceability processes are only as good as the weakest link. Therefore, it is important for everyone in the supply chain to understand the value of collecting and maintaining product information that supports, at the very least, one-step-forward—one-step-back traceability. The best practices for maintaining traceability for suppliers, retailers, processors, wholesalers, distributors, and, when possible, food service operators, are to capture agreed-upon traceability information, at critical traceability events, and make the data available via a virtual traceability network using either a 3rd-party solution provider or a company's own databases with standardized web service interfaces and messages.

Product barcodes can be scanned or read as an item or container enters or is shipped out of a distribution center, as it is received at a retail store or a food service operation, or as it is opened for processing or consumer display, each of which is an IFT-defined CTE (Bhatt and others 2013).

The main difference of barcoding compared with electronic messaging is the possibility of decentralizing data storage in combination with a search engine (or discovery service), and use of a Unique Product Identification key, barcoded or printed on the product itself, which may be used to access lot-based traceability data and product master data.

It is difficult to print the increasing amount of relevant data on the product package in human readable form. A unique production unit key (such as Global Trade Item Number [GTIN] plus a lot number) allows for accessing the data within a web application, for example. Electronic messaging technology enables all supply-chain partners to store relevant data within their own databases and provide the data to trusted partners or government authorities on request.

Global regulations and industry implementation

Regulatory landscape. The requirements of the traceability regulations vary worldwide. The regulations of different countries are detailed in Appendix , and described below.

With regard to recordkeeping, the countries of the European Union (EU) have the most comprehensive system; other countries have different (generally less encompassing) levels of recordkeeping requirements. Furthermore, countries require recordkeeping for reasons beyond food safety (sustainability and consumer information, for example) sustainability label.

In Canada, traceability regulations address only livestock; there are no explicit traceability regulations for food products. However, traceability of processed food products is verified through proper packaging and labeling, in accordance with the Consumer Packaging and Labelling Act for a given food commodity, as well as by the Food Safety Enhancement Programs (FSEP) for meat products.

The government of China is gradually establishing and improving national food safety laws and regulations with new requirements on food traceability. In 2009, the "Food Safety Law of PRC" and its implementing regulations was promulgated, requiring food producers to establish a purchase-inspection record system and a food-delivery inspection record system, and accurately record matters of law, or retain relevant notes on every purchase or sale (Liu and others 2012). Other regulations call for traceability requirements mainly at the trading event; there are no specific requirements for internal data collection. Also, there are no requirements for the collection of specific data relating to processing.

In the EU, driven partly by increasing consumer demands, there are many legislative requirements regarding traceability. There is variation among the rules regarding different aspects of traceability; most, however, require a one-step-forward–one-step-back approach as well as lot-based traceability. Motivation and scope of these rules cover sustainability and safety aspects as well as food and nonfood products. The general principles for food traceability, established in Article 18 of EC Regulation Number 178/2002, require that the traceability of food be established at all stages of production, processing, and distribution.

Beef and rice products are the only food products addressed in traceability requirements in Japan.

The Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) mandates, under its Beef Traceability Program for Domestic Beef, that an assigned number is carried through from livestock birth to the carcass at the abattoir, and the label or invoice with the final packaged product. With the assigned identification number, a consumer can access the information online and review the history of purchased beef products. The Rice Law of 2009 requires recordkeeping of transactions (purchases and sales) of rice and grains and informing consumers and business partners of origin information, to allow prompt identification of distribution route when needed. Other than the beef and rice products, there are no regulations for other food products on the traceability requirement.

In the United States, the Bioterrorism Act of 2002 (BT Act), and the recordkeeping requirements contained in the Act, represented a major step forward in the implementation of a product tracing system for FDA-regulated food products. People who "manufacture, process, pack, transport, distribute, receive, hold, or import food" in the United States, as well as foreign food transporters in the United States, are required to maintain records to identify previous sources and subsequent recipients of the food. Required records for food received and released must include: previous/subsequent source (including full contact details), description of food (brand name and variety), date received/released, lot or code number (if relevant), quantity and packaging. When food is released, records additionally must include information "reasonably available" identifying specific sources of each ingredient for each lot of finished product. In cases where food processors commingle ingredients such as flour from different suppliers, FDA accepts that manufacturers may not be able to identify one specific source (McEntire 2010).

Industry implementation. Other than EU countries which have clear food traceability requirements for recordkeeping in the

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regulations, various types of public–private partnerships exist to advance food traceability in different food sectors in different countries, such as the U.S. Dairy Traceability and the Meat and Poultry Data Standards Organization (mpXML 2010; USDT 2013).

In China, government agencies have worked with the industry associations and published several national standards and industry standards to provide the specific data collection requirements for some food sectors. These standards are recommended guides, and reflect best practices of the industry and the agencies. In 2013, the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) published the national standards GB/T 29373-2012 and GB/T 29568-2013 for fruits and vegetables, and fish/fishery products, respectively. These 2 standards require data collection in 3 areas: "received data" (defined as the data received from an upward supplier), "processed data" (defined as the data in the processing facility), and "output data" (provided to the downward supplier chain). During 2009 to 2011, the Ministry of Agriculture (MOA) published 6 agricultural industry standards that are required to be implemented in facilities producing and manufacturing cereal, fruit, livestock, tea, vegetables, wheat flour, and noodles. These 6 standards establish the traceability term and definition, requirements, data collection, data management, coding method, traceability identifier, and system operation self-inspection and management of quality and safety issues. With regard to data collection, specific data are required at different CTEs.

The MAFF published in 2007 the Japanese Handbook for Introduction of Food Traceability Systems, which provides comprehensive guidance to food standards in accordance with Japanese Agricultural Standards (JAS) and traceability requirements. This reference document outlines the types of information (such as product names, dates, and supplier/customer identifiers) needed to ensure traceability. The handbook also highlights the importance of connecting inputs to outputs to ensure that the critical links in traceability are not broken.

In the United States, several industry initiatives have evolved, and guidance documents were developed. The Produce Traceability Initative (PTI) is carried out by volunteer-led working groups in the areas of Implementation, Master Data, Technology, and Communications. The iniative is administered by the Canadian Produce Marketing Assn. (CPMA), GS1 US, Produce Marketing Assn. (PMA), and United Fresh Produce Assn. (UFPA). In 2010, GS1 published the "Traceability for Fresh Fruits and Vegetables Implementatin Guide" (GS1 2010). Several sector-specific guidances, produced by other organizations, are also available. These are: Guidance for Dairy Product Enhanced Traceability, Traceability for Dairy, Deli, and Bakery U.S. Implementation Guide, Traceability for Meat and Poultry: U.S. Implementation Guide; and U.S. Seafood Implementation Guide (mpXML 2010; NFI 2011; GS1US 2013; USDT 2013).

Each of these guidance documents is based on the use of GS1 global standards for supply-chain management and product identification. A guidance particularly focused on CTEs was published in 2010 as "mpXML Traceability Guide (mpXML 2010)." This mpXML guide provides detailed examples of information captured for events common to each supply-chain segment, and illustrates how CTE methodology could be adapted to fit industry practices, such as in-store product transformation and direct-store delivery of products.

Based on a review of government regulations, it appears that a one-step-up and one-step-down approach is a minimum traceability requirement. No current regulations have a specific data requirement along the entire supply chain. Furthermore, there are no uniform requirements for CTE/KDE information collection along the supply chain, either across different sectors or between countries. Other countries, such as China and Japan, have guidance/standards that focus on specific data collection and they address food safety, food sustainability, and customer information.

The U.S. industry initiative and guidance focus on implementation guidance using the GS1 system, which requires an electronic system and considerable investment for small businesses and which is focused mainly on food safety. There is no single document that addresses different food sectors in such a way as to identify the uniform data requirements for food traceability to allow all the stakeholders in the supply chain (farmers, processors, retailers, food service operators, distributors) to have guidance in identifying the CTE/KDE in their operations. This report identifies the CTE/KDE in 6 different food sectors and from the perspectives of different countries, shows the similarities and differences among them, and provides government agencies around the world and the industry with a uniform CTE/KDE data-collection framework.

Approach

Concept

As the concept is to cover several different food sectors' industry practices for traceability, we established a team comprised of experts from different stakeholders to provide the information, guidance, and recommendations.

- Assemble project workgroups:

Six project workgroups consisting of subject matter experts (SME) were assembled to provide sector-specific direction and content for the guidance document. A 7th workgroup was established to serve as an overview review.

The 6 sector-specific project workgroups represented the following food sectors: bakery, dairy, meat/poultry, processed food, produce, and seafood. An additional project workgroup served as overview reviewers.

The overview review workgroup was comprised of individuals having expertise in related sectors—distribution, transportation, retail, standards, technology, and regulatory—and able to provide other perspectives (for example, those of small-, mid-, and large-sized companies, international organizations, and farm input and ingredient suppliers). Other key stakeholders— Global Food Traceability Center (GFTC) Advisory Council members, and consumer advocacy group representatives—were also included in the overview workgroup.

- Develop a general traceability guidance framework:

KDEs and CTEs, defined by IFT in a pilot study for the U.S. FDA, were used as general baseline and were provided to the sector-specific working groups.

- Develop a sector-specific traceability guidance framework:

Project working groups applied the generic traceability framework to the respective food sectors. The SMEs provided content for sector-specific guidance and content for validation, verification, and refinement of the generic traceability framework.

- Update the generic traceability guidance framework:

Update the original generic framework using the similarities and differences observed within the specific traceability

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guidance frameworks for each sector to enhance its applicability and usability.

Baseline CTE/KDE framework

There are various points in a supply chain at which data capture is necessary to follow product movement. These points, referred to as CTEs, include:

- Shipping from one facility and receiving at another facility (Transportation);
- Changes that occur as products are manufactured or transformed during processing (Transformation); and
- Trace forward requires an accounting of all products; therefore, it is important for firms to also record the ways in which products exit the supply chain through depletion events (Depletion).
- At each CTE, KDEs must be captured to enable tracking and tracing of product movement through the supply chain.

The concepts of CTEs and KDEs were proposed by IFT in 2010, and considerable effort has been expended over the years by at least 100 stakeholders to clearly identify which data elements need to be provided to regulators in order to effectively trace food products throughout the supply chain (McEntire 2010).

This KDE/CTE framework provides information on the what, where, and when with respect to food products that traverse the supply chain. While each firm must maintain these records internally, these data also establish the links needed to connect supply-chain partners. Cross-sector collaboration must be encouraged to assist industry in sharing best practices and identifying a consistent implementation approach to product tracing for growers, producers, processors, distributors, retailers, and food service operators.

The CTEs and KDEs, along with the guidance to facilitate understanding and implementation, will allow individual supply-chain companies to correctly identify the CTEs that they are responsible for and ensure that KDEs for each CTE are captured and available for reporting as needed based on a specific request from regulatory officials. For definitions of CTEs and KDEs, refer to the IFT FDA pilot report (Bhatt and others 2013).

The following concepts are useful in defining CTEs and suggest that the identified KDEs be considered a minimum standard.

Transportation events. Those events that typically support external product tracing between supply-chain locations resulting from the physical transport of product by air, truck, rail, or ship from one supply-chain location to another supply-chain location.

- Shipping CTE: The event at which traceable product is dispatched from one defined location to another defined location. Shipping CTEs are typically followed by subsequent receiving events. Typically, this event occurs when a traceable product is transported by air, truck, rail, or ship from one supply-chain company to another supply-chain company, although it can also be between 2 separate locations within the same company.
- Receiving CTE: The event at which traceable product is received at a defined location from another defined location. Receiving CTEs typically occur in response to earlier shipping events. Typically, this event occurs when a traceable product is received at a location after being transported by air, truck, rail, or ship from one supply-chain company to another supply-chain company, although it can also be between 2 separate locations within the same company.

Transformation events. Transformation events support internal product tracing within the 4 walls of a company connecting incoming to outgoing shipments. Examples of transformation events are when product ingredients from one or more suppliers or sources are combined, or when a product is further processed such as by cutting, cooking, or repackaging.

- Transformation Input (T1) CTE: The event at which inputs (ingredients) from one or more suppliers or sources are combined and/or processed to produce a new traceable product that enters the supply chain. The objective is to capture the supplier, product identification (ID), and production unit of all ingredients used to create the new traceable product.
- Transformation Output (T2) CTE: The event at which outputs (finished product) are created and packaged for entry into the supply chain. The objective is to capture the Supplier, Product ID, and Lot/Batch Number (or equivalent) of the new output product and to ensure this information is available for capture in subsequent T1 events, Transport events, and Depletion events.

Every T1 CTE has a corresponding T2 CTE (that is, every input connected to its corresponding output). Transformation information may be consolidated to levels that the manufacturer feels are adequate to fully link traceable product being used during the Transformation process for the new traceable product being produced. Traceable product produced as an internal-use-only item during the Transformation process but then used during a subsequent step may not need to be recorded if adequate records are maintained that link the initial traceable product used and the final traceable product created.

Depletion events. Those events that capture how traceable product is removed from the supply chain. Depletion events consist of the following:

- Consumption CTE: Those events at which a traceable product becomes available to consumers. Examples of a consumption event include: when a case of fresh produce is opened and placed in bulk self-service bins at a retail grocery store, a packaged traceable product is sold at a point-of-sale (POS) register at a retail grocery store, or a case of seafood product is opened for use in preparing menu items in a restaurant. The objective is to capture the Supplier, Product ID, and Batch/Lot Number (or equivalent) of the traceable product and associate those with the Location, Date, and Time that the product became available to consumers.
- Disposal CTE: Those events at which a traceable product is destroyed or discarded or otherwise handled in a manner that the product can no longer be used as a food ingredient or become available to consumers. An example of a Disposal event is when a case of unopened fresh produce or other traceable product at a restaurant or retail store reaches its expiration date and is properly discarded. The objective is to capture the Supplier, Product ID, and if possible, the Batch/Lot Number (or equivalent) of the traceable product and associate those with the Location, Date, and Time that the product was removed from the supply chain without becoming available to consumers. While not used in a trace-back investigation, the Disposal CTE is important during a trace-forward/recall investigation to prove that 100% of items are accounted for.

Table 1 shows a summary of these CTEs and KDEs. While global product identification, Lot, Batch, or Serial number, in

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Table 1–IFT suggested key data elements (KDEs) for capture and recordkeeping at critical tracking events (CTEs).

	Critical tracking events (CTEs)					
	Transportation (exchange of goods)		Transformation (creation/manipulation of products)		Depletion (exit from system)	
	Shipping	Receiving	Input	Output	Consumption	Disposal
Currently required KDEs						
Event Owner (firm submitting information)	X	X	X	X	X	X
Date/Time	X	X	X	X	X	X
Event Location	X	X	X	X	X	X
Trading Partner[a]	X	X	X			
Item (the good)	X	X	X	X	X	X
Lot/Batch/Serial Nr.	X	X	X	X	X	X
Quantity	X	X	X	X	X	X
Unit of measure	X	X	X	X	X	X
Linking KDEs						
Activity Type (for example, Purchase Order, Bill of Lading, Work Order)	X	X	X	X		
Activity ID (number associated with PO, BOL, Work Order)	X	X	X	X		
Transfer type[b]	X	X				
Transfer number[b]	X	X				
Lot/Batch Relevant Date[c]	X	X	X	X	X	X
Carrier ID	X	X				
Trailer number	X	X				

[a] In the event of a Shipping CTE, the trading partner is the immediate subsequent recipient of the shipment. In the event of a Receiving CTE, the trading partner is the immediate previous supplier of the product. In the event of a Transformation CTE, the trading partner is the supplier of the input into the Transformation.
[b] If the Activity Type and ID are not linked to a particular shipment of a product (that is, a purchase order that is fulfilled by multiple shipments over time), then the Transfer Type and ID are used to indicate the particular shipments that are linked to the Activity Type and ID.
[c] If there is a different Lot/Batch designation on a consumer-level product, such as a "best-by" date, it must link to the manufacturer-assigned lot number.

combination with Date, Time, and Location can be used to trace a product shipment across CTEs, these numbers were seldom communicated or captured throughout the supply chain; this was particularly true as product moved downstream toward consumers. In the absence of such information, other documents can be used to trace a product shipment across the supply chain. One data element that is of particular relevance and which is not required by current regulation is an "Activity ID," which is an identifier associated with an "Activity Type" such as a Purchase Order (PO) or Invoice Number that can be used to link products between supply-chain partners.

It should be noted that this guidance document recommends the following CTEs and KDEs as best practices regardless of the size of the operation. However, small- and mid-sized businesses may not be able to satisfy some or all of these guidelines because of resource constraints.

Table 1 serves as the common denominator for all the CTEs and KDEs identified within the sections for each food sector later in this document; some sectors, however, collect more data than represented by the following CTEs and KDEs.

The capture of at least the minimum required KDEs as products travel through the supply chain will improve the ability to trace products. These data, particularly the PO number and Bill of Lading (BOL), are useful for identifying product transported between trading companies when supplier-established product identification and lot information is not available. The capture of supplier-provided product identification and batch/lot should be required for all events as the strongest means of "linking" all CTEs that relate to a product shipment. However, Activity Types such as a PO can be used as a weaker substitute to link product shipments from CTE to CTE when product Identification and Batch/Lot information is not available.

Because there are a number of barriers in the near term (such as resource constraints), initially the capture and reporting of product identification, batch, lot, or serial numbers for all Depletion and Transportation events should be encouraged as a best practice. In their absence, the Activity ID and Type should be recorded. However, using Activity IDs to trace products results in more data (compared to using product identification, batch, lot, or serial numbers), and therefore it is only of limited use when used in conjunction with an analytical technology platform by the regulators instead of being manually sorted and queried. Furthermore, following products through a string of Activity IDs obfuscates the manufacturer- (or other transformer-) assigned lot numbers until they are revealed by the manufacturer (or transformer). Clearly, capturing product identification and Lot Numbers along the supply chain is the best way for investigators to rapidly identify the CTEs reporting information for the same product shipment across the supply chain.

SME elicitation

Seven workgroups consisting of SMEs from particular sectors and other related sectors (see below) were assembled. To identify SMEs for these workgroups, an extensive search was conducted, by actively reaching out to individuals who had extensive experience with food traceability in particular sectors, different trade associations, global businesses and organizations, small and medium food businesses, and experts from different countries.

Six Food Sector Workgroups:

- Bakery sector
- Dairy sector
- Meat/Poultry sector
- Processed foods sector
- Produce sector
- Seafood sector

Overview Review SME Working Group:

Related Sectors:

- Distribution sector
- Transportation sector

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- Retail sector
- Standards sector
- Technology sector
- Regulatory sector

Other Perspectives:

- Different size of companies: small, mid, and large sized
- International organizations
- Global organizations
- Farm input and ingredient suppliers

Other key stakeholders:

- Members of the GFTC (Advisory Council) who had an interest
- Consumer advocacy groups

All of the participants thought the project would be very beneficial to the food industry globally and could provide good information about the industry's practice on food traceability to the agencies around the world. A total of 55 SMEs from 11 countries were invited to participate in this project. These experts were affiliated with food manufacturers, distribution firms, government agencies, nongovernmental organizations (NGOs), retailers, technology providers, and trade associations. Countries represented by these experts included Canada, China, Denmark, Germany, Italy, Japan, Macedonia, Norway, Turkey, the United Kingdom, and the United States. Each food-sector workgroup had at least included 2 SMEs designated for making written contributions for the –sector-specific CTE/KDE information, and 2 SMEs focused on reviewing content and providing additional information or input/recommendations. The overview workgroup included the reviewers from all other stakeholders in food traceability to provide additional input/information for these specific 6 food sectors. All SMEs were requested to review the draft document when it was completed.

Bakery

This section describes the typical supply chain of bakery food product along with a discussion on how the baseline CTE/KDE framework applies within this sector.

Supply chain

As described below, the bakery industry can be described in many different ways, either by the type of products made, their position along the value chain, or customer segment.

Bakery products can be found in the following forms:

- Ingredients
- Dry mixes or kits
- Fillings, Icings
- Pastries, Croissants, Sweet rolls
- Bread, Buns, Rolls (for example, French breads)
- Crackers
- Cookies, Bars
- Cakes, Cupcakes
- Tarts, Pies
- Biscuits, Scones, Muffins

The products can be found at one or more of the following positions in the value chain:

- Ingredients (domestic and imported)
- Mixes, Kits
- Ready-to-bake (that is, batter/dough)
- Ready-to-use (that is, filling/icing)
- Ready-to-serve
- Retail self-serve bulk
- Retail prepackaged
- Thaw and serve

The bakery industry services the following customer segments (see Figure 1):

- Industrial
- Food service
- Retail bakery
- In-store bakery
- Retail self-serve bulk
- Retail prepackaged
- Outlets (thrift stores, animal feed, food bank/donations)
- Vending machines

The bakery industry has a supply chain that is similar to other food industry segments, although with some unique challenges. A simplified process flow for the bakery industry supply chain is shown in Figure 2.

Specialized CTE–KDE framework for the bakery sector

Raw material harvesting and/or processing. Bakery products typically contain a combination of agricultural components (for example, flour, sugar, fruit, dairy products, eggs, nuts, and spices) and nonagricultural components (for example, leavening agents, salt, flavorings, colors, emulsifiers, preservatives, primary and secondary packaging, flour treatment agents, and flour enrichments). Traceability during the production of nonagricultural components is fairly straightforward, as follows:

- Identify previous source of raw materials
- For raw material imports of agricultural and nonagricultural goods, record identity of event owner's country of origin
- Record lot codes and quantities of ingredients received; and tie those ingredient lot codes to where they were used in production
- Record lot codes of finished product packaging
- Record quantities and lot codes of ingredients discarded
- Record lot codes of finished products
- Record lot code and quantity shipped to next recipient
- For transports of bulk and nonbulk items, record the trailer or rail car information. For bulk items, the vessel is the direct contact packaging item to deliver it to the next customer.

However, for agricultural components, traceability is more complicated than this. Ideally, all components would be able to be traced back to the field, orchard, flock, or herd. Nuts and fruits are shipped from orchards to accumulating locations, where they are comingled in a container, silo, or shipping vessel. Traceability typically is not maintained from the growers. Similar issues occur with other agricultural products.

Flour, sugar, and oil are major components in bakery products. For high-volume industrial bakeries, these ingredients are typically received by bulk tanker or rail car and stored at the bakery in bulk silo or tank systems. The silo or tank systems are emptied infrequently, if at all; thus, comingling of lot codes occurs in the silos. Each time an ingredient is drawn from the silo, a mixture of lot codes is removed. If a food safety issue were to occur with one of the lots, all products made after that lot was introduced into the silo could be implicated.

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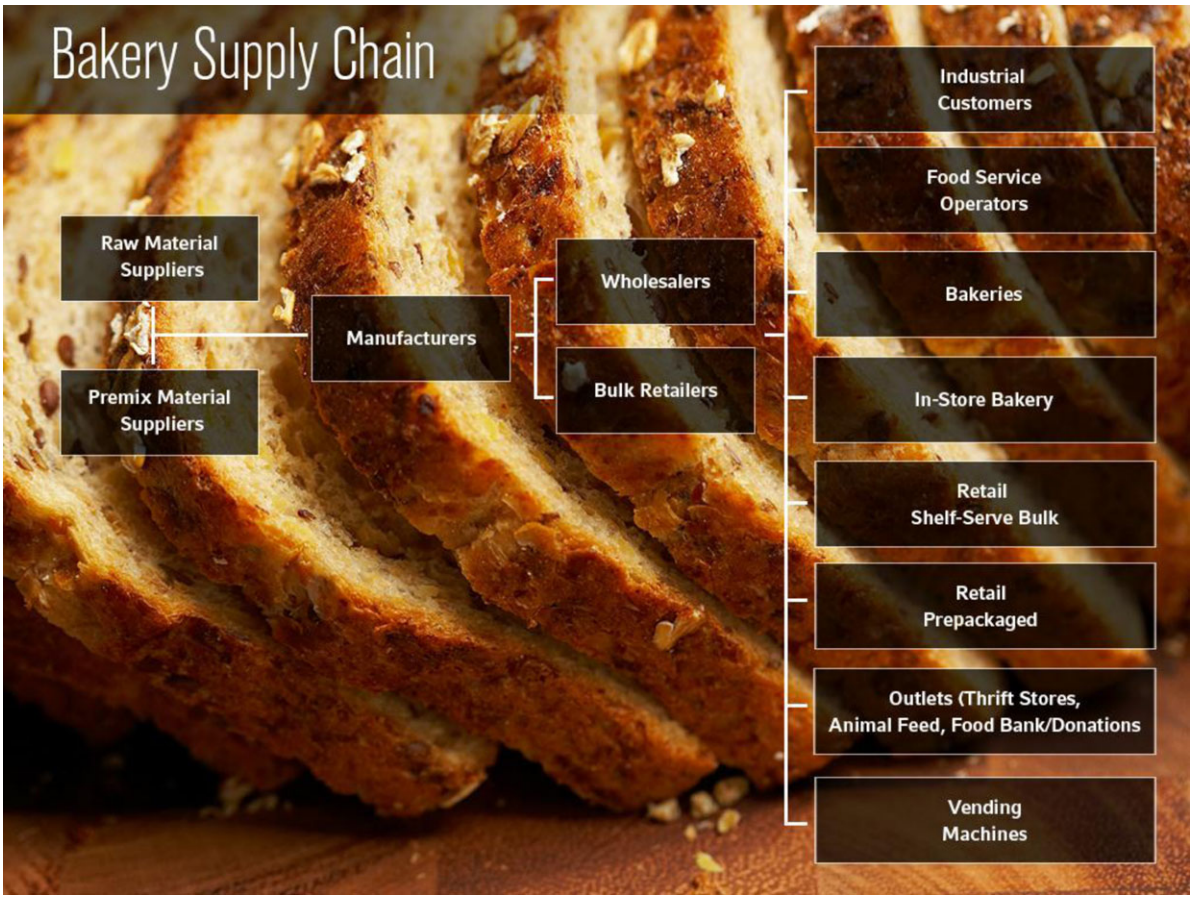

Figure 1–Stakeholders in the bakery sector supply chain.

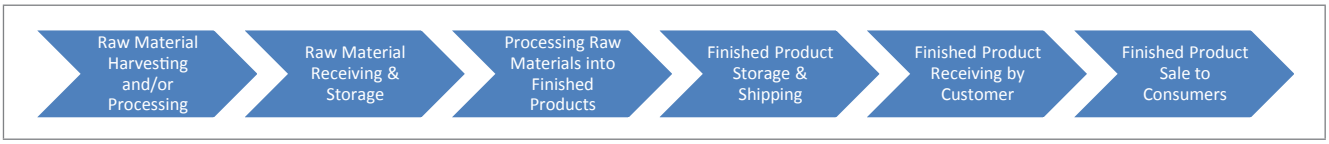

Figure 2–A simplified process flow diagram for the bakery sector.

CTEs for raw material harvesting and/or processing include Harvesting, Discarding damaged or spoiled materials, Shipping and Receiving agricultural and nonagricultural components, processing components into raw materials, and Shipping finished raw materials. KDEs include Quantities and Lots at each CTE, Previous source, and Subsequent recipient. More information and examples of generic CTEs and KDEs are provided in the Section "Background."

Raw material receiving and storage. Before a raw material is received into a manufacturing facility, the shipment's content, quantity, and lot codes should be verified against the shipping documents, typically the BOL, invoice, or packing slip. (Three other pieces of information from the shipper would be the carrier's name and emergency contact information and how the product was packaged, 50 pound bags, 25 pound boxes, and so on. This was specifically called out in the Bioterrorism Act under section 306 and has updated the FD&C Act to require this information.) If there are discrepancies, the shipment should be rejected. Receipt of raw materials is a CTE for this step in the supply chain.

Once a shipment is received, the raw materials should be affixed with an identifying label that includes a code name and/or number, possibly a pallet identifier, received date, discard date, lot code, allergen content status, and, when needed, the storage requirements (for example, refrigerated, frozen, or ambient). The product identification number and quantity for each lot code received should be recorded in a receiving log, which may be paper or electronic, a KDE for this step in the supply chain.

Storage procedures vary in sophistication, depending on whether or not the facility has an electronic warehouse management system (WMS). With a manual system, raw materials may or may not have designated storage slots. Allergens should be taken into account, through the use of written standard operation procedures (SOPs), when determining where to store raw materials so that cross-contact does not occur. Raw materials should be arranged in a manner that allows for first in–first out (FIFO) or first expired–first out (FEFO) stock rotation. When raw materials are moved to staging for production, a best practice would be to record the lot codes and quantity moved so that all locations of the lot can be tracked. This record would be a KDE.

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With an electronic WMS, each pallet or container is typically given a barcode label that includes complete information on the identity of the material, the lot code, any allergen content, and the quantity present. This barcode enables tracking of the material throughout the facility. The WMS will assign a storage slot for that particular pallet or container based on established put-away rules. The put-away rules include information on allergen content, temperature requirements, shelf-life, and stock rotation rules for that particular item. As a package of raw material is removed from storage for staging for manufacturing, the barcode will be scanned, and the traceability data will be recorded electronically. Such data are a KDE.

Manufacturing usage. When an ingredient or primary packaging material is received on the manufacturing floor, a CTE should be verification of the quantity and lots received against the issuing document. Any discrepancies should be immediately addressed and no further action will be taken until the traceability discrepancy is resolved. A best practice would be to only issue to the manufacturing floor the exact quantity of ingredients needed to complete the scheduled production run. This will decrease the quantity of returns that must be accounted for at the end of the production run.

As the manufacturing process consumes the primary packaging components or ingredients, a CTE is the recording of specific lots used in each batch of premix, work in progress, or finished product. Rework must be lot-coded and treated the same as any ingredient for traceability purposes. If the facility is unable to match the ingredient or primary packaging component to a specific batch, then at a minimum the manufacturer must tie all raw material lot codes to a specific lot of finished product. A CTE that must be performed at the completion of the production run is to account for shrink (loss of product during processing), the quantity of finished goods produced, and the quantity of raw materials that will be returned back to the warehouse.

Transfer from manufacturing to a warehouse. Depending on the type of bakery, the warehouse may be internal, or a client's warehouse; in the case of a fresh bakery, the finished goods may be shipped straight to an in-store bakery or retail store.

When shipping to an internal warehouse, a KDE is the recording of the lot code and quantity of the pallets shipped. If a WMS system is in place, a barcode will be placed on each pallet identifying the license plate of the vehicle, lot code, product, and the quantity of cases on the pallet. When received by the warehouse, a CTE is verification of the count on each pallet and the lot code against what was stated by manufacturing. If a company has a WMS system, the KDE of recording the location slots will be performed by the WMS program to enforce FIFO or FEFO and other put-away rules. If there is no WMS system, the KDE for recording the location slots and quantity of each pallet must be performed manually, either through electronic or paper means, to ensure FIFO or FEFO is followed. Product will be warehoused until ready for staging for shipping.

If the warehouse belongs to a client or if the finished goods are shipped straight to an in-store bakery or retail store, then customer requirements for shipping should be followed.

Shipping. When a PO has been placed, the warehouse is notified of the needed quantity to fulfill the order. If a WMS system is in place, it indicates to the warehouse team which pallets must be pulled to satisfy FIFO or FEFO requirements. If the system is manual, care is taken to ensure FIFO or FEFO is followed. A KDE for staging of the order is to record the quantity of each lot pulled to fulfill the order. Once sufficient product is pulled to fulfill the requirements of the PO, a CTE is to verify the lot code and count of each pallet prior to placing onto the shipping vessel. If a WMS system is used, the pallets are scanned into the system against a PO, and the pallet count and lot code is connected to the next recipient in the food chain. If the system is manual, this same information must be recorded. A CTE is the generation of an invoice that reports the name and address of the next recipient, the quantity ordered, the quantity shipped, and all associated lot codes.

The carrier company name and emergency contact information should also be recorded as part of the shipping information; how the products are packaged (for example, individually wrapped 12 boxes per case) should also be recorded.

Receipt of the order. A CTE by the next recipient is to record KDEs such as lot codes and associated pallet and/or case quantities upon receipt of the shipment.

Dairy

Supply chain

All dairy products originate from the animal and its milk, in raw form. Figures 3 and 4 shows the typical supply chain for liquid milk and CTEs/KDEs from farm to consumer.

Specialized CTE–KDE framework

The following are examples of simple manufacturing processes common in the dairy industry. In each example, we identify the places in the process where a new KDE–Lot Identifying Mark will have to be recorded, and list typical bulks/ingredients/materials that would need to be added to the process. In most cases, there are relatively few places in the process where Lot Identifying Marks need to be recorded.

References to BOL or Load Info or Farm Tickets intend to include the information required by the U.S. Bioterrorism Act as follows:

- Identify the immediate previous sources, whether foreign or domestic, of all foods received, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety (for example, Brand X Cheddar Cheese, rather than simply cheese; date received; quantity and type of packaging (for example, 12-ounce bottles); and identify the immediate transporter previous sources including the name, address, telephone number and, if available, fax number and e-mail address. Persons who manufacture, process, or pack food also must include lot or code number or other identifier if the information exists.
- Identify the immediate nontransporter subsequent recipients of all foods released, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety; date released; quantity and type of packaging; and identify the immediate transporter subsequent recipients, including the name, address, telephone number and, if available, fax number and e-mail address. Persons who manufacture, process, or pack food also must include lot or code number or other identifier if the information exists. The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

Typical KDEs and CTEs, by process area. Most dairy food processes, including cheese, milk and whey powders, ice cream, nov-

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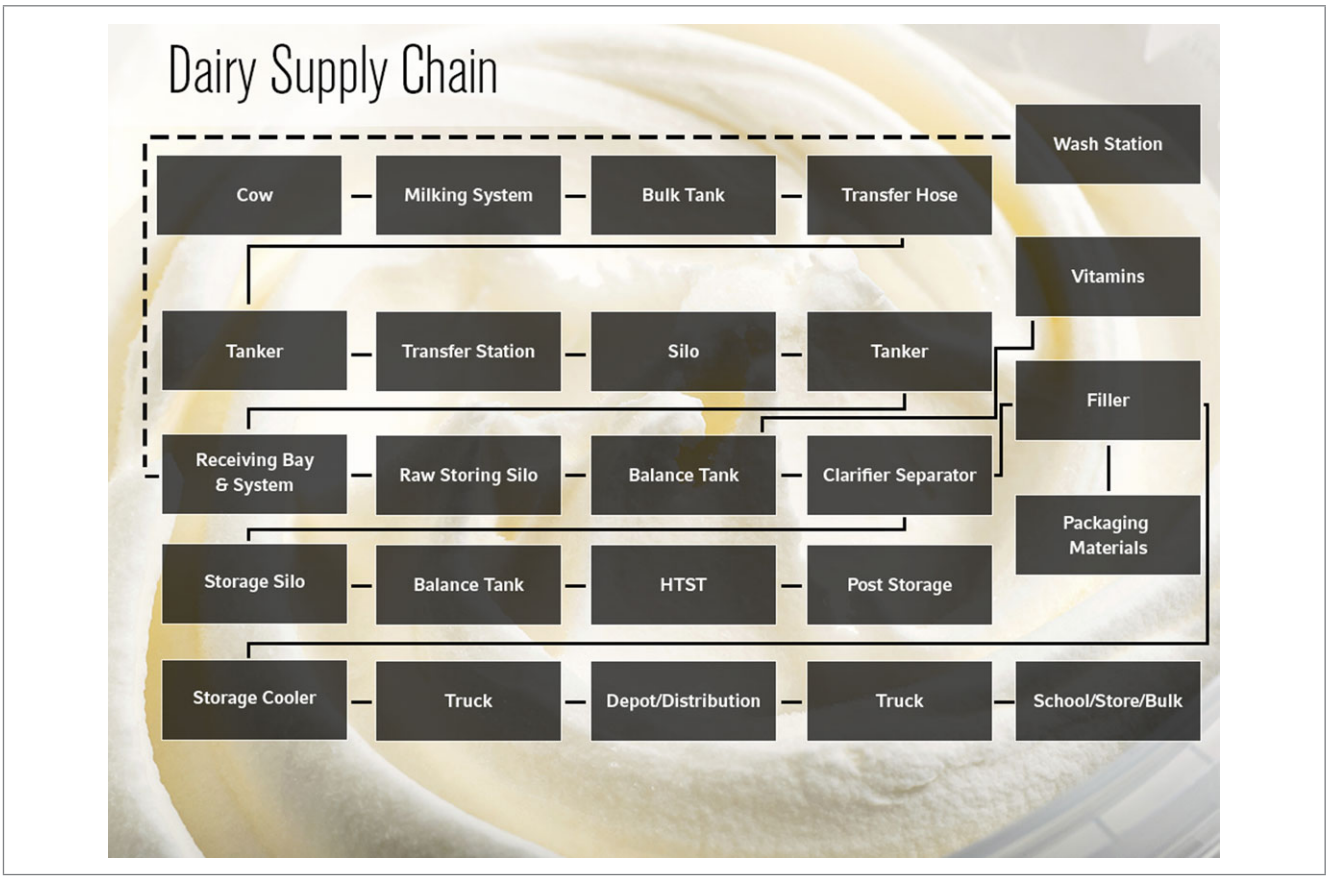

Figure 3–Typical liquid milk supply chain.

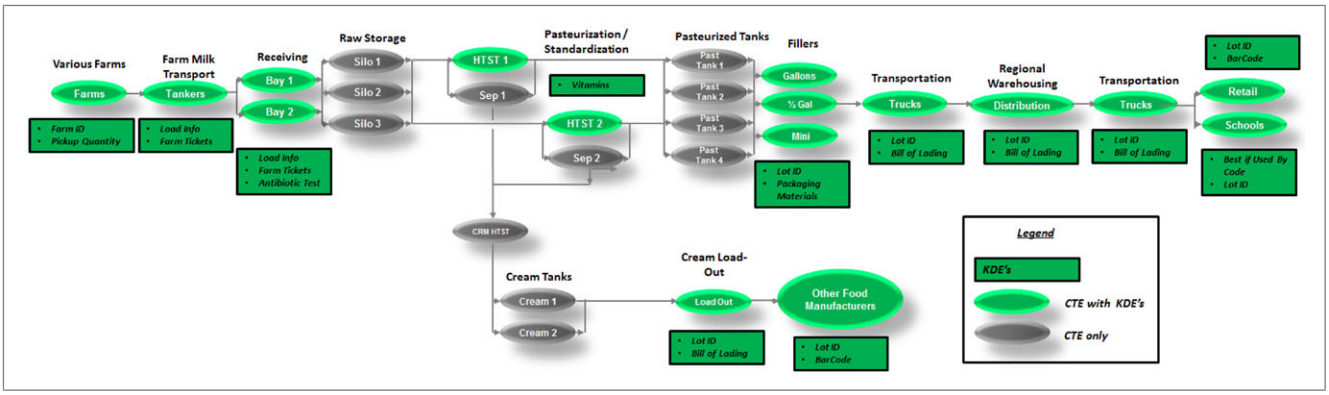

Figure 4–Typical fluid milk CTEs and KDEs from farm to consumer. Note: The green boxes contain the KDEs or points at which outside ingredients or materials are integrated into the process.

elties, clutured products, butter, fluid milk, yogurt, and other dairy beverages and products, typically include the following traceability recordkeeping needs:

Receipt of bulk milk

- Farm number
- Carrier/Hauler identification
- Driver Identification
- List of Farm Identification in Load
- Time Load was Received
- Quantity
- Receiver/Tester
- Silo Destination for Load

Dry warehouse

- Event Owner (firm submitting information)
- Date and Time
- Event Location (address of facility)
- Trading Partner
- Item (the good)
- Lot ID
- Quantity
- Unit of Measure

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Process areas

- KDEs—When ingredients are added to the process
  - Event Owner (firm submitting information)
  - Date and Time
  - Event Location (address of facility)
  - Trading Partner
  - Item (the good)
  - Lot ID
  - Quantity
  - Unit of Measure
- CTEs—as product flows through the process
  - Start time
  - End time
  - Source unit
  - Destination unit

CIP (Clean in Place records)

- CIPs recorded to create breaks in LOT IDs in the process.

Final Product Packaging

- KDEs—Packaging materials used that contain product
  - Records kept
    - Event Owner (firm submitting information)
    - Date and Time
    - Event Location (address of facility)
    - Trading Partner
    - Item (the good)
    - Lot ID
    - Quantity
    - Unit of Measure
- KDEs—Finished goods LOT ID assigned and marked on the product
  - Records kept
    - Event Owner (firm submitting information)
    - Date and Time
    - Event Location (address of facility)
    - Trading Partner
    - Item (the good)
    - Lot ID
    - Quantity
    - Unit of Measure

Commonalities in the dairy foods industry with other foods. [Content for this section has been adapted from the U.S. Dairy Traceability guide (USDT 2013)]

Most of the traceability within the dairy foods industry is common with other foods. The dairy foods industry utilizes many food products from all the other food industries in their processes. So these food products would be handled the same in the dairy industry as in other industries.

Commonalities with other food industries:

- Receiving ingredients into warehouse for use in process
- Batching operations, inclusion of outside ingredients
- Flow of food products through the process (overall concept of traceability in the process)
- Recording of Lot IDs as ingredients are added to the process
- Incorporation of packaging materials into the production of the final product
- Tracking of final products through the transportation, distribution, and retail chain.

(With some exceptions, especially around fluid milk)

Special considerations for the dairy foods industry. [Content for this section has been adapted from the U.S. Dairy Traceability guide (USDT 2013)]

The following specific areas are common in the dairy foods industry and should be considered when listing KDEs–Lot Entry Points:

- Raw Milk Receiving—When receiving raw milk, the receiving facility should consider each farm on a truck as a lot of product received. The facility should have, or have access to, the farm name and address of the farmer for the complete KDE record.
- Milk Hauler Responsibility—The records of the Milk Hauler performing the farm pickups are paramount to making a recall work and are the 1st step in creating a successful traceability program.
- Using Farm ID—The Farm ID is often used as the identifier for the farm load. This can be helpful to trace the loads, since this number is issued by a regulatory agency and is used in inspections and other records. However, many cooperatives and other dairy businesses assign their own farm ID as well.
- Raw Milk Pooling—When milk is picked up from the farm, loaded into silos or tanks and reshipped to dairy foodsplants, it is the responsibility of the milk pooling facility to keep the records of the farm loads as they relate to the tankers shipped.
- Whey Pooling—When whey or permeate is pooled from various cheese manufacturing facilities, it is treated as a bulk loadout product at the cheese facility, and is received by the whey processor as any other bulk product. The Lot identity is created at the cheese facility, and the same Lot identity is used to receive the whey into the processing facility. If the whey is pooled at a pooling or reloading station, the station must keep the correlated records as would any other dairy processing facility.
- Fluid Milk Distribution—Many times various Lot IDs of milk are delivered in the same delivery, especially when being delivered to smaller stores or convenience stores. Each container is marked, however, with a batch or Lot ID.
- Rework—Reworked product is common in the dairy industry but complicates traceability. Consider rework as any other ingredient or product.

Examples of Rework:

- Fluid milk filler flushes saved for use in chocolate milk.
- Skim milk powder off-spec and reworked into the dryer.
- Cheese fines added back into the cheese.
- Ice cream batches either off-spec or excess is added to other batches.

Meat and Poultry

Supply chain

For traceability purposes, the meat and poultry sector can be further divided into 3 subcategories: beef, pork, and poultry. Other meats that are consumed at lower volumes than beef, pork, and poultry would follow similar traceability practices. Figures 5 and 6 shows the typical stakeholders in the meat and poultry sector supply chain.

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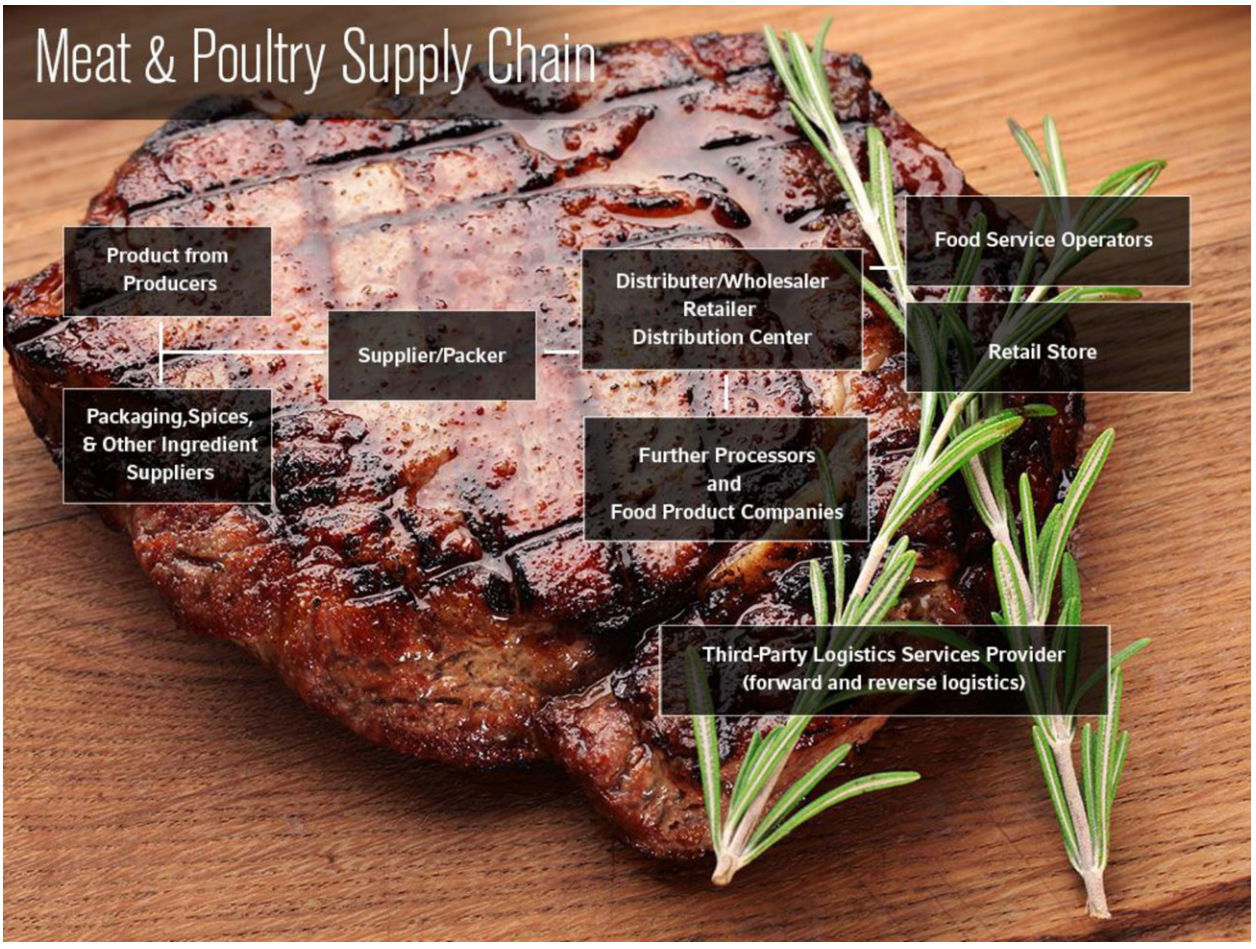

Figure 5–Stakeholders in the meat and poultry sector supply chain.

While supply chains for specific meat and poultry commodities vary greatly, the overarching flow of food is fairly similar (see Figure 6 as example). It usually starts with the birth of the animal, followed by maturing, slaughtering, butchering, processing, distributing, and POS. Establishments where a CTE could take place include producer facilities (farms), abattoirs, rendering plants, dead stock collection points, border posts, quarantine stations, warehouses, distribution centers, cold storage facilities, retail grocery stores, and food service operator restaurants (WOAH 2013). It is also noted that there are difficulties in tracking animals and/or their parts after slaughter, especially at nonslaughter cutting houses such as retail meat markets or food service cutting operations. There are several intermediate CTEs within this overarching supply chain that also have an impact on the traceability of the food such as shipping, receiving, comingling, and disposal.

Specialized CTE-KDE framework

- Poultry
  - CTEs
    - Egg Delivery
    - Eggs to Incubator
    - Hatched Eggs
    - Unhatched Eggs
    - Chick Delivery to Farm
    - Chick Placement
    - Shipment of Feed to Farm
    - Delivery of Feed to Farm
    - Mature Broilers/Spent Hens
    - Broiler Pickup
    - Broiler Delivery
    - Broiler Dead on Arrival (DOA)
    - Broiler Harvest
    - Minimally Processed Meat
    - Shipping to Partner
    - Receiving by Partner
    - Nonmeat Ingredient
    - Packaged Finished Product
    - Shipping to Distributor
    - Receiving by Distributor
    - Shipping to Retailer or Food Service Operator
    - Receiving by Retailer or Food Service Operator
    - Retail POS
    - Case Opened by Food Service Operator
    - Product Disposed as Unusable Waste
  - KDEs
    - Who
      - Owner of Breeder Farm
      - Owner of Hatchery
      - Owner of Broiler Farm

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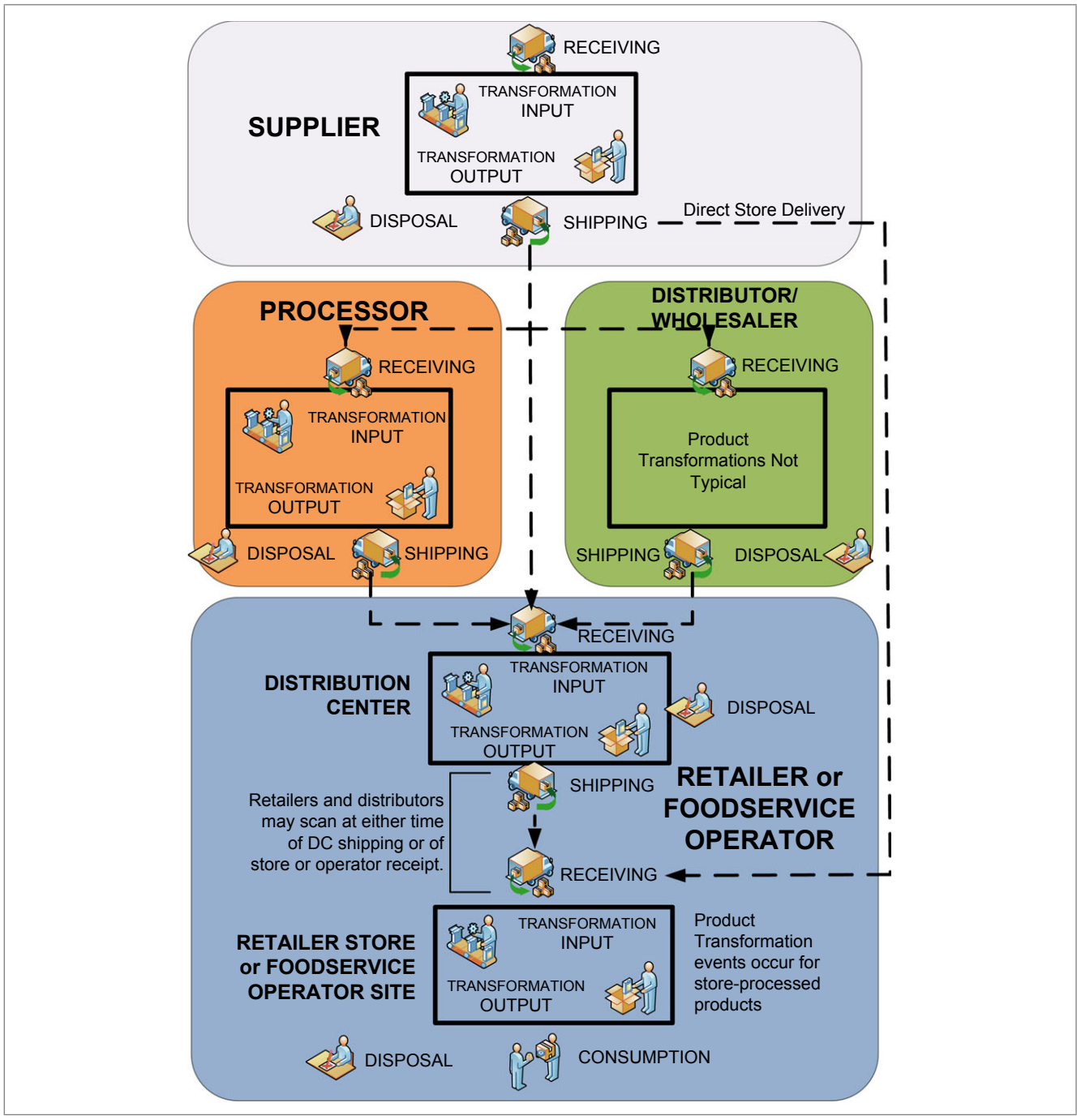

Figure 6–Critical tracking events for meat and poultry.

- Owner of Feed Mill
- Owner of Processing Plant
- Owner of Cold Storage
- Owner of Retail
- Owner of Food Service Operation

- Where
  - Location of Hatchery
  - Location of Broiler Farm
  - Location of Feed Mill
  - Location of Processing Plant
  - Location of Cold Storage
  - Location of Retail DC/Store
  - Location of Food Service DC/Restaurant
- When
  - Date
  - Time
- What
  - Eggs
  - Chicks
  - Feed
  - Broilers/Spent Hens

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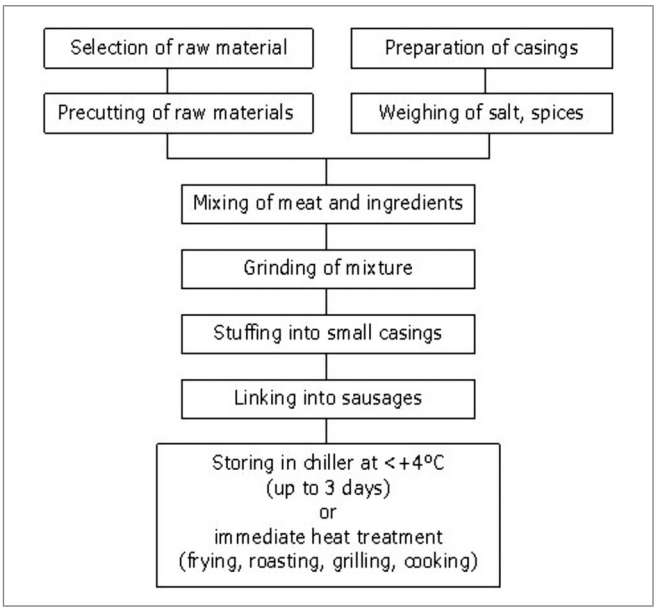

Figure 7–Example of meat/poultry processing (sausages, for example).

    - Nonmeat Ingredients
    - Packaging
    - Processed Product
  - Identifiers
    - Breeding stock
    - Flock ID
    - Product
    - Batch Number/Lot Number
    - Use-By Date
    - Sell-By Date
  - Activity Types
    - Purchase Orders
    - Delivery Identification
    - Process Identification
    - Cycle Identification
    - Feed Order Number
    - Ticket Number
    - Work Order Number
    - Carrier Name
    - Trailer Number
- Beef
  - CTEs
    - Feed
    - Shipping to Processing Plant
    - Receiving by Processing Plant
    - Live Animals
    - Minimally Processed Meat
    - Nonmeat Ingredients
    - Packaged Finished Product
    - Shipping to Distributor
    - Receiving by Distributor
    - Shipping to Retailer/Food Service Operator
    - Receiving by Retailer/Food Service Operator
    - Retail POS
    - Case Opened by Food Service Operator
    - Product Disposal as Unusable Waste
  - KDEs
    - Who
      - Owner of Feed Lot
      - Owner of Processing Plant
      - Owner of Cold Storage
      - Owner of Distributor
      - Owner of Retailer Store
      - Owner of Food Service Operation
    - Where
      - Location of Feed Lot
      - Location of Processing Plant
      - Location of Cold Storage
      - Location of Distributor
      - Location of Retail Distribution Center (DC)/Store
      - Location of Food Service Distribution Center (DC)/Restaurant
    - When
      - Date
      - Time
    - What
      - Cattle
      - Feed
      - Nonmeat Ingredients
      - Packaging
      - Processed Product
    - Identifiers
      - Animal Identification
      - Animal Batch
      - Product
      - Batch Number/Lot Number
      - Use-By Date
      - Sell-By Date
    - Activity Types
      - Purchase Order
      - BOL
      - Feed Order
      - Cycle Identification
      - Ticket Number
      - Work Order Number
      - Carrier Name
      - Trailer Number
- Pork
  - CTEs
    - Feed
    - Hogs
    - Shipping to Processing Plant
    - Receiving by Processing Plant
    - Minimally Processed Meat
    - Nonmeat Ingredients
    - Packaged Finished Product
    - Shipping to Distributor

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    - Receiving by Distributor
    - Shipping to Retailer/Food Service Operator
    - Receiving by Retailer/Food Service Operator
    - Retail POS
    - Case Opened by Food Service Operator
    - Product Disposed as Unusable Waste

- KDEs
  - Who
    - Owner of Finishing House
    - Owner of Processing Plant
    - Owner of Cold Storage
    - Owner of Distributor
    - Owner of Retailer Store
    - Owner of Food Service Operation
  - Where
    - Location of Finishing house
    - Location of Processing Plant
    - Location of Cold Storage
    - Location of Distributor
    - Location of Retailer
    - Location of Food Service Operator
  - When
    - Date
    - Time
  - What
    - Hogs
    - Feed
    - Nonmeat Ingredients
    - Packaging
    - Processed Product
  - Identifiers
    - Product
    - Batch Number/Lot Number
    - Animal Identifier
    - Use-By Date
    - Sell-By Date
  - Activity Types
    - Purchase Order
    - BOL
    - Feed Order
    - Cycle Identifier
    - Ticket Identifier
    - Work Order
    - Production Date
    - Trailer Number
    - Carrier Name

For simplicity of implementation and to maintain a focus on the more critical, immediate gaps in tracing capability closer to the consumer, the CTEs/KDEs identified above are those of primary importance subsequent to the feeding lot. In addition to these CTEs/KDEs, some other information may be collected, and may include number of dead animals, and medication for all poultry, beef and pork operations, vaccination information for the beef and pork chains, the nursery, cow/calf operation, stocker operation, and sale barns.

Processed Foods

This section describes the typical supply chain of processed foods as well as develops a specialized CTE/KDE framework for this sector. It must be noted that several other sectors like the dairy, meat/poultry, and bakery sectors, overlap at some point with the processed food sector when they are used as input ingredients to create a finished processed food product.

Supply chain

Processed foods have increasing challenges in the traceability arena these days. The global trade of foods and ingredients has become a diverse and complex operation (See Figure 8). Consumers continue to look for innovation in food products along with good nutritional value and ethical ingredients, as well as continuing to desire traditional products. To satisfy customer demand and maintain market share, processed food manufacturers seek competitively priced ingredients from developing countries; and, global trade allows sourcing of ingredients from all over the world.

However, due to the diversity of agricultural operations and practices, quality assurance systems, and country regulations, the processed food sector faces challenges in identifying domestic and international ingredient sources, ensuring the safety of those ingredients and foods, and tracing products when addressing foodborne illness situations (for example, investigation, recall) or managing their supply chains.

The vast harvest-to-table food system includes agricultural production and harvesting, aquaculture, wild seafood harvesting, holding and storing of raw materials, food manufacturing (formulation, food processing, and packaging), transportation and distribution, retailing, food service, and food preparation in the home (Floros and others 2010). A processed food product might consist of an agricultural commodity (for example, coffee, corn, grain, oil, rice, sugar, tea, or wheat), fresh produce (vegetable or fruit), protein (for example, meat, dairy, or seafood), seasonings (spices, for example), food colors, vitamins/minerals, processing aids, or other components (Floros and others 2010). In addition, a processed food product may include ingredients from countries thousands of miles away.

The supply chain of the processed food sector starts with the raw materials. The raw materials may include silo materials, raw ingredients, processing aids, and packaging materials. Silo materials may include raw agricultural products such as wheat, rice, and other grain products. Raw ingredients may include colorings, emulsifiers, salt, spices, sugar, vitamins, and other ingredients, which may be sourced in bags, boxes, or totes. Processing aids and packaging materials may be shipped as pallets, boxes, or totes. After inspection for quality assurance and other recordkeeping processes, are stored in a warehouse, and follow the FIFO or FEFO for production.

When manufacturing begins, the prep room/kitchen orders the material as specified for certain recipes and formulations, and the raw materials are transferred in designated amounts to the manufacturing floor. After processing, which may include premixing, emulsifying, heat treatment, or cooling, the product is packaged using specified packaging and shipped to internal or offsite storage. Distribution channels for processed foods may include transportation to a warehouse, retailer, or food service site, school, restaurant, vending machine, or other business operation.

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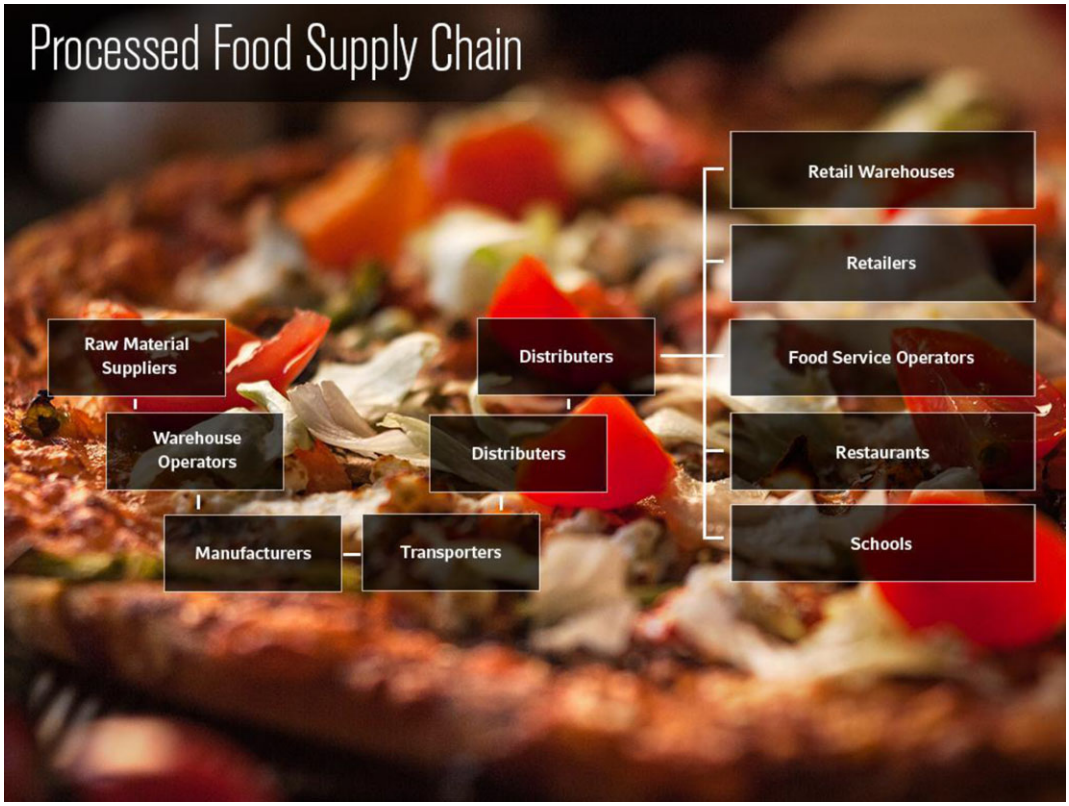

Figure 8–Stakeholders in a processed food supply chain.

Specialized CTE-KDE framework

Although it may appear simple, the supply chain for processed foods is much more complex than described above (shown in Figure 8). Thus, KDEs at CTEs are essential to ensure traceability internally and externally.

Most processed food manufacturers, particularly contract manufacturers, do not have single-formula products. A medium-sized company may have several dozen formulas/recipes that are tailored to different customer needs or preferences; this is especially likely for a processor that produces private-label goods. In addition, it is not uncommon for food manufacturers to use different comanufacturers for different product lines, which adds further to the complexity in a food traceability system.

Ordering of material. For this CTE, quantity, name, or other identifier of the product, and expected receipt date are identified as KDE.

Receipt. For this CTE, the received materials need to be verified against the purchase record/BOL. KDEs are identified as below:

(a) Raw Materials (includes silo materials, processing aids, and all packaging materials)
(b) Method of Receiving, including verification against purchase orders and bills of lading (silo, boxes, pallets, totes, for example)
(c) Event Owner (warehouse, receiving, operations, brokers)
(d) Systems of physical identification (date codes, stamps, labels, inkjet coders, RFID systems, electronic coding systems)
(e) Lot/Batch code identification
    (i) Batch code of materials received/supplier lot code system (lot size is critical and varies greatly from supplier to supplier. It is important to understand how the supplier tracks their ingredients (lots) that go into their products)
    (ii) Internal lot code system (that is, batch code of intermediate materials assigned internally for production tracking)
    (iii) Customer lot code system or batch code of finished goods (assigned to consumer units)

Storage

Storage CTEs should record the following KDEs:

(a) Records: Physical stock reconciliation against stock records
(b) Item Identification, Quantity, Location, and Status (such as transfer status [in transit, still at the vendor, and others] or production status) (unrestricted/available to ship, in test, quality hold, restricted/not available to ship)
(c) Compliance of Inventory Control System:
    (i) FIFO or
    (ii) FEFO systems or
    (iii) LIFO (last in first out)
    (iv) or hybrid system
(d) Ingredient Hold System
    (i) The process and reconciliation for ingredients
    (ii) Supplies put on hold
    (iii) Management of test compared with production run ingredients

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(1) Status of soft hold, where product can move internally
(2) Status of hard holds, in which nothing should move

(e) Manual compared with electronic WMS.

(i) Connection of internal identification and supplier codes and lots

Production.

(i) Event owner (kitchen prep room, ordering of materials against specification and orders)
(ii) Amount of raw materials routed to production
(iii) Lot/Batch Code identification

(i) Assignment of new code recorded against the receiving code to ensure traceability

(d) Records systems (to track codes, amounts, usage, time of production, production line of the ingredient usage, and others)

(i) Reconciliation of material used compared with recipe: Verify that correct amount of material was used and code date/lot properly recorded on batch sheets
(ii) Main record system compared with comanufacturers' systems
(iii) Partial ingredients or packaging material record returning to inventory after production

(a) Intermediate materials (work in progress [WIP]), at Premix/Preweigh
(b) Intermediate materials, batch at production
(c) Record to keep partial batches (use of different batch/lots in different production dates)
(d) Rework

(i) Raw material or component recirculation information, such as the location and the usage
(ii) Record for Held WIP, how managed and tracked

Packaging. Packaging material has become a critical raw material over the years. Since packaging materials typically are produced in large lots, it is very essential that the manufacturers keep detailed KDE information at this event.

There are 3 CTEs for which KDEs need to be collected:

(a) Intermediate materials batch, after packaging, into primary unprinted container
(b) Intermediate materials batch, at secondary packaging
(c) Intermediate materials batch, after secondary packaging

The KDEs that need to be collected are:

- Raw Packaging Material Supplier Information
- Lot Code
- Location (manufacturing site and processing line)
- Packaging material, quantity/usage
- Product Code
- Product Name
- Product Batch/Lot Number

It is important that the quantity, lot number, and supplier information be recorded for any unused packaging materials, for their future usage. If the products are repacked into different configurations, and new Universal Product Codes (UPCs) and batch code are assigned, the linking information must be recorded so that the new UPCs can trace back to the original product information.

Shipping. The finished products are dispatched to internal or offsite storage locations.

(a) Lot/Batch Code identification

(i) Assign new code with production date, lot code, line ID, time of production, expiration or use-by date, and establishment number, for USDA-regulated products
(ii) Tracking of pallet codes with code date on product

(b) Reconciliation of all pallet units

(i) Serial Shipping Container Code

Outside warehouse.

(a) Reconciliation of all pallet units
(b) Multiple deliveries based on orders
(c) Serial Shipping Container Code
(d) Number of Traded Units, per dispatch unit

Customer.

(a) Lot/Batch Code identification

Other KDEs to consideration.

(a) Event Owners

(a) Record information
(b) Store records
(c) Access records

(b) Records

(a) Date/Time coding
(b) Lines
(c) Quantities
(d) Usage
(e) Records development
(f) Records control
(g) Records types
(h) Records corrections
(i) Recorded storage and access
(j) Records discrepancies (ordered compared with amount received, display shipper complexities) and management of damaged, out of date, destroyed, or returned product; the source to obtain warehouse damage and unsaleable information

(c) Raw Materials

(a) Raw materials generic names
(b) Vendor/Supplier name
(c) Vendor/Supplier batch/lot code system
(d) Quantities ordered, received, stored, used, returned, damaged, or lost
(e) Delivery date
(f) Supplier internal ID numbers
(g) Certificate of Analysis (COA) data

(a) Intermediate Materials, additional information

(a) Start time of mixing, usage
(b) Quantity mixed
(c) End of time of mixing
(d) Lost, damaged
(e) Returned, unused materials to warehouse

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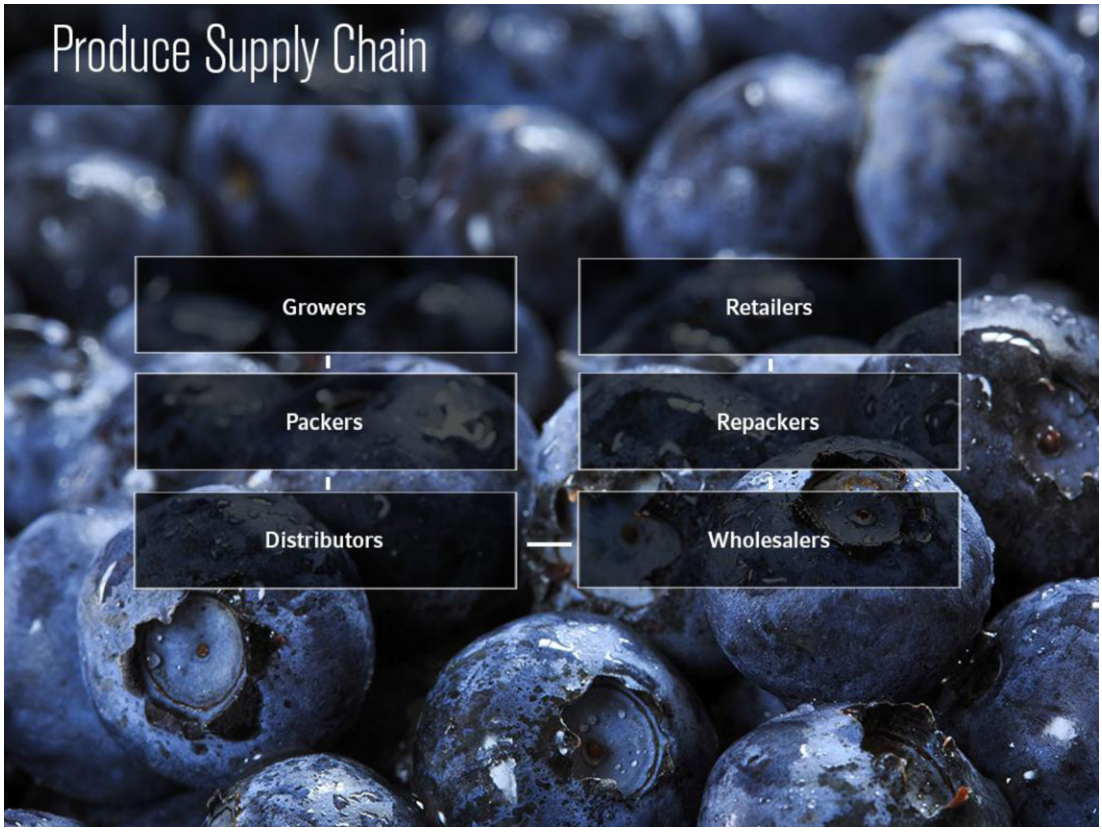

Figure 9–Stakeholders in a produce sector supply chain.

Produce

This section describes the typical supply chain for the produce sector as well as develops a specialized CTE/KDE framework for this sector.

Supply chain

As shown in Figure 9, the most likely groups of stakeholders involved in the production and distribution of fresh produce are presented.

Specialized CTE-KDE framework

Grower KDEs

(a) Commodity
(b) Variety
(c) Harvest Date and Time
(d) Product Identifier (unique code assigned to the particular product)
(e) Harvesting Field Lot Number
(f) Harvesting Crew Name
(g) Harvest or Production Lot Quantity/Weight (pounds or tons)
(h) Grower name

Packer KDEs

Harvest side:

(a) Grower Name
(b) Commodity
(c) Variety
(d) Harvest Date and Time
(e) Product Identifier (unique code assigned to the particular product)
(f) Harvesting Field Lot Number
(g) Harvest/Production Lot Quantity/Weight (pounds or tons)

Packing side:

(a) Commodity
(b) Variety
(c) Product Identifier (unique code assigned to the particular product)
(d) Product/Pack Style, Size, Quality
(e) Packing Date and Time
(f) Packing Lot
(g) Pallet Tags/Case Tags
(h) Shipping Manifest
(i) Detail Pallet Tags on Shipment
(j) Packer Name/Facility
(k) Packing Lot Quantity/Weight

Distributor KDEs

Packing side:

(a) Shipping Manifest
(b) Pallet Tags/Case Tags
(c) Commodity
(d) Variety
(e) Product Identifier (unique code assigned to the particular product) (GTIN)
(f) Product/Pack Style, Size, Quality
(g) Detail Pallet Tags on Shipment

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(h) Packing Date and Time
(i) Packer Name and Location
(j) Packing Lot Quantity/Weight

Distribution side:

(a) Commodity
(b) Variety
(c) Product Identifier (unique code assigned to the particular product)
(d) Product/ Pack Style, Size, Quality
(e) PU Number (Pick Up number or Order Number; normally the identifier number for the sale transaction from the vendor)
(f) Customer Name
(g) Customer PO Number
(h) BOL
(i) Shipping Quantity/Weight
(j) Pallet Tags/Case Tags
(k) Shipping Date/Time
(l) Detail Pallet Tags on Shipment

Wholesale KDEs (the intermediary between the grower/distributor and retailer/restaurant)

Distribution side

(a) PU Number
(b) PO Number
(c) BOL
(d) Distributor Name
(e) Commodity
(f) Variety
(g) Product Identifier (unique code assigned to the particular product)
(h) Product/Pack Style, Size, Quality
(i) Receiving Date and Time
(j) Quality Control Information
(k) Pallet /Case Tags

Customer side

(a) Customer PO
(b) Order No
(c) Commodity
(d) Variety
(e) Product Identifier (unique code assigned to the particular product)
(f) Product/Pack Style, Size, Quality
(g) Wholesale BOL
(h) Shipping Date and Time
(i) Shipping Quantity/Weight
(j) Pallet Case Tags

Repacker KDE (an entity that takes prepacked produce and repacks it into different configurations)

Repacker Side

(a) Work Order
(b) Input Lot Numbers (BOL, PU Numbers, and others)
(c) Input Product/Pack Style, Size, Quality
(d) Output Product/Pack Style, Size, Quality
(e) Commodity
(f) Variety
(g) Product Identifier (unique code assigned to the particular product)
(h) Loss Report
(i) Pallet/Case Tags

Special considerations

(1) Growers/packers might have direct access to POS customers through partnerships, thus that scenario does not include the need for a distribution entity or any other 3rd party in the delivery of product.
(2) In any given transaction, there may be 2 or more entities involved but which do not receive or take possession of the product. For example, brokers may buy product from Distributor A and sell it to Customer X, but the product may ship directly from Distributor A. For tracking purposes, the events need to be considered, since different PU or PO numbers may be involved.
(3) Repackers may run several lots from different growers/distributors in a single repack, creating a commingling situation.
(4) A unified naming convention for a product could be very useful to homogenize product names across the distribution chain.
(5) Homogeneous tracking information capabilities (pallet tags/case tags) may also be very useful, especially for traceability in wholesale and terminal market operations.

Seafood

Supply chain

[Content for this section has been adapted from the U.S. Seafood Traceability guide (Natl. Fisheries Inst. 2011)]

Traceability for seafood products from their source to the point of consumer purchase would require the following CTEs at the processing facility:

- Product Creation (including catch/harvest)
- Product Packaging/Repackaging
- Product Processing
- Product Shipping
- Product Receipt
- Product Consumer Sale
- Product Depletion

Traceability programs are needed across the entire supply chain, from catch or harvest to processors, suppliers, importers/exporters, and distributors, and should include aquaculture farms, vessels, retailers, and food service operators so that recalls, if necessary, can be conducted efficiently and effectively to identify affected foods (Table 2 shows the role of different entities in the seafood distribution channel). Traceability elements may include shipping logistics unit information, lots, pallets, cases, and consumer items with data elements.

Figure 10 shows the complexity of conventional seafood distribution channels, and the interfaces between wild harvest and aquaculture, and how animals from both of these harvesting methods may be processed within the same facility into finished goods.

Specialized CTE-KDE framework

CTEs along with KDEs are:

- Product Receipt (Unique Identification of Shipment linked to Unique Product Identification, Date Received, Origin of Product)

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Table 2–Role of different entities in the seafood distribution channel.

Role	Activities	Examples
Primary roles		
Hatchery/Farms/Vessels	Grow and ship, possibly harvest	Suppliers of seafood
Wild caught/Vessels	Catch and ship	Suppliers of seafood
Broker	Manage relationship between supplier and customer, but does not take possession of product	Agent
Processor	Harvest, process, repack, package, label, store, sell, ship	Seafood packer, supplier
Retail store	Receive, store, process, package/label, and display; sell to consumer	Grocery store, supermarket, grocery chains, open market
Retail, food service, distributor, or wholesaler	Receive, store, sell, ship	Retail distribution center, Food service distribution center, Import/Export warehouses
Food service operator	Storage, prepare, cook, sell to consumer	Restaurants, entertainment venues, institutions
Support roles		
Feed suppliers	Produce and ship	For hatcheries and farms
Packing material supplier	Produce and ship	Suppliers of packing material (crates, bags, boxes, labels, bins, clamshells, and others)
Ingredient supplier	Produce and ship	Breading, spice, additive (for example, citric acid) manufacturers
Third-Party logistics service provider	Transport, store	Truck, Rail, Ship, Air
Regulatory organizations	Compliance oversight	Customs, Inspection, and Grading agencies
Service providers	Maintenance of farm sites Checking nets Chemical treatments (for example, disease treatment) Measurement of environmental data	

Adapted from NFI (2011).

- Product Ingredient (Unique Identification of ingredient along with Batch/Lot Number or Serial Number)
- Product Creation (Unique Identification of Product, Batch/Lot Number or Serial Number)
- Product Shipping (Unique Identification of Shipment linked to Unique Product Identification, Date Shipped, Shipment Destination)
- Pallet Configuration (Unique Shipment ID with Unique Product ID aggregation, Batch/Lot Number or Serial Number, Quantity)
- Consumer Unit Depletion and/or POS (Unique Product ID, Batch/Lot Number link, Date Purchased, Quantity)

Requirements for shipment traceability. The traceability KDEs required are the same for all seafood products, both variable-weight and fixed-weight, and are the same whether the seafood is refrigerated, frozen, or shelf-stable. Best practices for seafood shipments involve monitoring the following KDEs and are included in the paper-based manifest and the electronic advance shipment notice (ASN):

- Batch/Lot or Serial Numbers
- Unique Identifier (such as a GTIN in a GS1 system)
- Quantity Shipped
- Shipping Date
- Receiving Dates
- Ship From and Destination Locations

In addition, other useful information such as the following may be included as appropriate for recordkeeping:

- Stock Keeping Unit (SKU) or other supplier product identification reference
- Production Date, if product is for retail store-processing or food service use
- Catch Date or Sell-By Date or Best-By Date, if applicable
- Labeling and tracing of regulatory requirements for the producer, copacker, or product seller. For example in the United States, this may include an USDA Establishment Number or USDA Country-of-Origin Labelling Statement or ISO Country Number(s), if applicable
- Labeling for credence attributes such as: USDA labeling for wild-caught or farm-raised, halal or kosher certification, organic or sustainability logos

Maintaining traceability for product from live seafood providers. Live seafood providers deliver product in various logistic units. Each logistic unit should be individually traceable. Information used to ensure traceability includes:

- Provider Identity
- Accurate farm/vessel information depending on species of the seafood received (such as FAO area and alpha code [FAO 2014])
- PO Number or Live Receiving Ticket of received seafood
- Date of Shipment and Receipt
- Carrier Name and Trailer Number
- Natl. Shellfish Sanitation Program (NSSP) Tag for Live Shell stock
- Catch Certificate (EU requirement)
- Quantity

Live animal/seafood product lots must be traceable. This is accomplished by associating the seafood Lot Identification Number and Batch/Lot Number of the output product. Note that the data described are focused on KDEs that support the sharing of CTEs.

Maintaining traceability for other product ingredients. Batters, breading, seasonings, marinades, salt, moisture-retention agents, citric acid, packaging materials, and many other product inputs are used in the production process by suppliers. These product lots must be traceable. This is accomplished by associating each Product Lot Identification Number (such as GTIN, if used) and Batch/Lot Number of the output product it is used to produce (see the Processed Food section for additional details).

Product sourced from other suppliers should be identified by the Batch/Lot Numbers provided by the supplier (such as the GS1 GTIN, if used). The assignment of unique identifiers for each product traded (that is, all product configurations) is the

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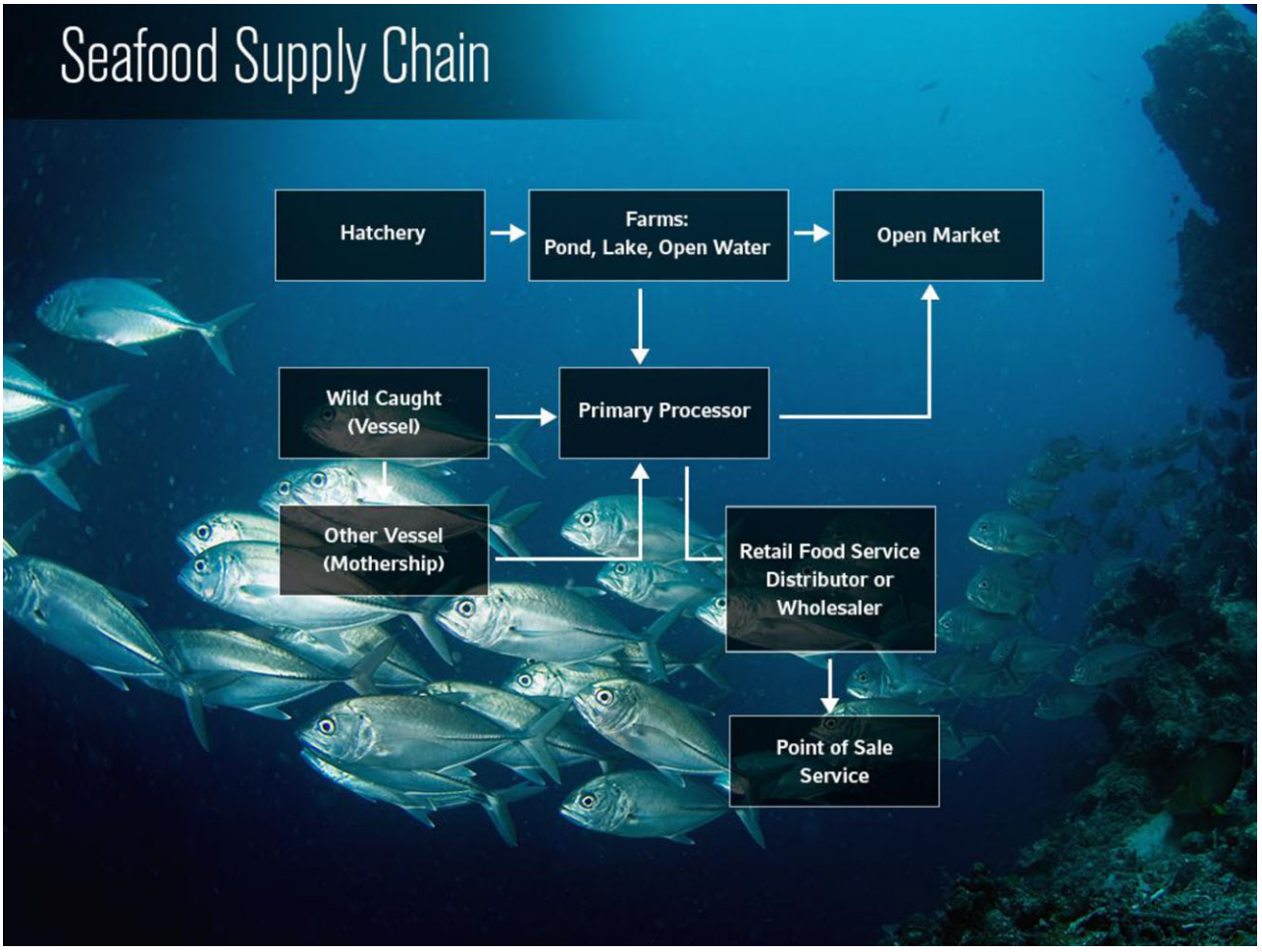

Figure 10–A seafood distribution channel.

responsibility of the brand owner and must be recorded in the supplier's internal systems prior to being processed or traded.

Unique Identifiers and Batch/Lot or Serial Number information must be provided on individual case labels. The Unique Identifiers and Batch/Lot or Serial Number of each input product must be associated with the Unique Identifiers and Batch/Lot Number of the output product.

Generic Framework 2.0 (Update of Original Framework)

Similarities and differences across sectors

Comparison of the 6 industry sectors (bakery, dairy, meat/poultry, processed food, produce, and seafood), shows similarities and differences in KDEs and CTEs across these sectors. The similarities can be used to update the original generic framework for improved applicability across all sectors. The differences can be used to highlight areas that call for special considerations or may suggest gaps in traceability linkages. Table 3, 4, and 5 present the similarities and differences across the 6 sectors, and Table 6 is the update of the original framework.

Comparing 6 sectors in terms of supply chain, they are very much similar, except the produce sector does not have raw material/bulk material supplier, but has packer and repacker in the supply chain. The meat/poultry sector has additional packer and repacker stakeholders as well (Table 3).

There are some differences on the CTEs among the 6 sectors. Dairy and processed food sector don't have creation CTE which includes harvest, hatch, growth and catch events. Bakery,

Table 3–Comparisons of simplified supply chains.

Stakeholder	Bakery	Dairy	Meat and poultry	Processed food	Produce	Seafood
Farm, grower, hatchery	X	X	X	X	X	X
Raw material, bulk supplier	X	X	X	X		X
Processor, manufacturer	X	X	X	X		X
Packer			X		X	
Distributer, wholesaler	X	X	X	X	X	X
Repacker			X		X	
Retailer, food service	X	X	X	X	X	X
Consumer	X	X	X	X	X	X

X = applicable stakeholder for that sector.

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Table 4–Comparison of simplified critical tracking events (CTEs).

Category	CTE	Bakery	Dairy	Meat and poultry	Processed food	Produce	Seafood
Creation	Harvest, hatch, grow, catch	X		X		X	X
Transformation	Separate, sort		X			X	X
Transformation	Combine, mix, repack, comingle	X	X	X	X	X	X
Transformation	Process, production	X	X	X	X		X
Transformation	Batching	X	X	X	X		X
Transformation	Pack, package	X	X	X	X	X	X
Transportation	Load, fill, order	X	X	X	X		X
Transportation	Ship, transport, receive, and unload	X	X	X	X	X	X
Transportation	Store, warehouse	X	X	X	X		X
Transportation	Return	X		X	X		
Depletion	Discard, dispose, loss	X	X	X	X	X	X
Depletion	Use or Sell to consumer	X	X	X	X	X	X

X = applicable CTE for that sector.

Table 5–Comparison of simplified key data elements (KDEs).

Category	KDE	Bakery	Dairy	Meat and poultry	Processed food	Produce	Seafood
Who	Immediate Supplier	X	X	X	X	X	X
Who	Event Owner	X	X	X	X	X	X
Where	Origin, Location, Destination	X	X	X	X	X	X
What	Product, Commodity	X	X	X	X	X	X
What	Packaging Type, Materials, Style	X	X	X	X	X	X
What	Variety, Species	X	X	X	X	X	X
What	Batch, Lot Code, Sell-by Date, Use-by Date	X	X	X	X	X	X
What	Quantity, Amount	X	X	X	X		X
When	Date	X	X	X	X	X	X
When	Time	X		X		X	
Who	Subsequent Customer	X	X	X	X	X	X
Who	Trailer, Carrier, Transporter	X	X	X	X	X	X
Link	Bill of Lading, Invoice, Packing Slip, Load Info, Farm Tickets, Purchase Order, Work Order	X	X	X	X	X	X
Optional/Not Current Best Practices	Allergy Content, Temperature Requirements, Shelf life, Consumer Loyalty Card, Antibiotic Testing Results, Antimicrobial Residue Testing, Loss Report, Chemical Treatments (for example, Disease Treatment), Measurement of Environmental Data	X	X	X	X	X	X

X = applicable KDE for that sector.

Table 6–Updated Generic framework (2.0).

		Critical tracking events			
		Creation	Transportation	Transformation	Depletion
Key data elements		Harvest, hatch, grow, catch	Load, fill, order, ship, return, transport, receive, unload, store, warehouse	Process, production, package, batch input or output, separate, sort, combine, mix, repack, comingle, rework	Sell to consumer, consumption, discard, dispose, lose
Who	Event Owner	X	X	X	X
	Trading Partner (supplier, customer)		X		
	Trailer, Carrier, Transporter		X		
What	Item, Good, Product, Commodity, Variety, Packaging Type, Packaging Materials, Packaging Style, Batch, Lot Code, Sell-by or Use-by Date, Quantity, Unit of Measure	X	X	X	X
When	Date, Time	X	X	X	X
Where	Origin, Event Location, Product Source, Product Destination	X	X	X	X
Link	Activity, Bill of Lading, Invoice, Packing Slip, Load Information, Farm Tickets, Purchase Order, Work Order	X	X	X	

meat/poultry and processed food sectors don't have separate/sort event but dairy, produce and seafood do. Produce is the only sector which doesn't have process/production event, batching event, load/fill, order in the transportation event, as well as store warehouse (Table 4).

The KDE collection is very uniform across the 6 sectors (Table 5). It shows that these KDEs are applicable to all 6 food sectors which will allow regulators to create more uniform recordkeeping requirements. There are differences in some data collections in the areas which are not critical for the traceability, but as recordkeeping for food security, sustainability, or quality management requirements.

The update of original framework of CTE/KDE (Table 6) shows that additional CTE as creation is added in the framework. Also, detailed transaction information is included for each event as creation, transportation, transformation, and depletion.

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The KDE clearly includes the 4W (Who, What, When, Where) and 1L (Link) for each CTE. The update framework simplifies the structure by grouping the KDEs under each 4W and 1L, which will help the regulators and industry to capture the information much easier and clearer.

Conclusion

In summary, the generic list of CTEs and associated KDEs seem to be applicable to all 6 sectors evaluated in this document. While some particular events do not occur in some sectors, or some KDEs were not collected for certain sectors, and nomenclature may differ from one sector to another, from a traceability perspective, food is handled and distributed across the value chain in a fairly consistent manner. This creates an opportunity for regulators to develop more uniform recordkeeping requirements across all foods rather than using a piecemeal approach. It also provides guidance to the industry with regard to the current best practices among their peers and to gain a deeper appreciation of the complexities of implementing good traceability practices. This guidance document presents the current best practices in the industry for 6 overarching food sectors, and it summarizes the similarities and differences among them in traceability. As regulators around the world work to develop new requirements for food traceability, this document can be a blueprint for what is practical for industry compliance. That is, all food sectors studied in this document, are currently capable of tracking transportation, transformation, and depletion CTEs by recording the "who, what, when, where, why, and how" KDEs. However, it is not currently being implemented in a consistent and uniform manner across all sectors. The document also contains cautions relating to the small nuances that need to be considered when developing new regulations and recordkeeping requirements. This guidance recognizes that special considerations are needed at times (for example, for small businesses) and that on occasion special considerations hinder effective traceability (for example, exclusion of point of source or sale from a traceability system).

With the review and input of leading industry experts, this guidance also helps balance one of the most important and significant data gaps that regulators face when developing new policies—"What is the industry currently capable of and how much can realistically be asked of them?" This document can facilitate more balanced, effective, science-based, and cost-conscious policies.

Whether a new food system stakeholder is looking to build or participate in a traceability system, or a large multinational corporation would like to update existing traceability systems, this guidance document can provide valuable context and content. Companies working within a single food sector, such as a fishing vessel or tomato repacker, will find that sections of this document are valuable starting points for understanding how to refine and strengthen traceability practices.

More extensively involved stakeholders, like those dealing with multiple food commodities, such as distributors and retailers, for example, may use this guidance for an updated version of a CTE–KDE-based framework that is applicable to most foods. Uniform applicability to most foods allows such multicommodity companies to avoid a traceability using redundant, cost-prohibitive one–sector-at-a-time.

Impact and Next Steps

Capturing, storing, and sharing information up and down the distribution channel (external traceability) and within a company (internal traceability) in a timely and accurate manner and with interoperable and scalable concepts is a critical goal for global traceability throughout the food system. Minimum requirements for traceability will always depend to a certain extent on human readable information. However, the best practice for all supply-chain partners is to build a traceability process that allows for electronic data capture, storage, and retrieval of critical product traceability information (CTEs and KDEs). As an example, a challenge for industry is to institute a reliable traceability system that can be implemented at a small operation as well as at larger and sometimes more complex distribution systems. Similarly, programs must be developed that can be used in facilities where the work is seasonal and where workers may have low literacy, and where harvests, operating capital, and resources for capital investment remain feasible.

This guidance document also demonstrates a need for more research in this area. While the 6 sectors studied in this report are representative of the food supply in today's marketplace, there are several others (such as oils, seeds, and nuts) that should be investigated. However, there may be unique food systems or stakeholders that have not been evaluated in this report.

Another area for further research is pilot-testing the self-reported best practices within the industry. Pilots could be conducted to follow the paper trail and records within an industry segment to verify and validate the CTEs—KDEs within each sector. Such pilots would help by further elaborating on current industry capabilities. A literature review and an environmental scan of more recent, current, and planned pilots within the industry would provide a starting point for the research. Along the same lines, there needs to be education and training for capacity building within each sector, especially small and medium enterprises. Such learning could also require the development and design of a tool that could help the food industry and regulators interact and customize the updated CTE-KDE framework to better meet their individual needs.

The intent of this guidance document is to bring us one step closer to developing harmonized and interoperable global food traceability standards and regulations. The political, social, economic, geographic, and environmental factors that influence the adoption and implementation of a harmonized and interoperable system still need to be evaluated. Several current initiatives, including those of government agencies, attempt to create uniform requirements for traceability recordkeeping. This guide serves as a catalyst for such activities and provides a CTE-KDE-based framework, identifying when (CTEs) and what (KDEs) need to be tracked in order to enable whole chain traceability across multiple sectors. This is simple enough to be applicable globally, yet comprehensive enough to be useful and effective.

Acknowledgments

This section lists all the SMEs who volunteered their time and expertise on this project. Only those who explicitly gave us permission to be named in this report are listed below. A total of 55 individuals were actively involved, providing stakeholder input, review, and comment. IFT is extremely appreciative of the time, effort, and care that these individuals gave to this project.

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Abbreviations

ASN	Advance Ship Notice
BOL	Bill of Lading
CFDA	Chinese Food and Drug Administration
CIP	Clean in Place
COA	Certificate of Analysis
CTE	Critical Tracking Event(s)
DOA	Dead on Arrival
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FBO	Food Business Operator
FD&C	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FEFO	First expired–first out
FIFO	First in–first out
GFTC	Global Food Traceability Center
GMO	Genetically Modified Organism
GTIN	Global Trade Item Number
HACCP	Hazard Analysis and Critical Control Points
IFT	Institute of Food Technologists
ISO	Intl. Organization for Standardization
JAS	Japanese Agricultural Standards
KDE	Key Data Element(s)
MOA	Ministry of Agriculture
NGO	Nongovernmental organization
NSSP	Natl. Shellfish Sanitation Program
PO	Purchase Order
PTI	Produce Traceability Initiative
PU	Pick-up
QA	Quality assurance
RFID	Radio Frequency Identification
SKU	Stock Keeping Unit
SME	Subject matter expert
SOP	Standard operating plan(s)
T1	Transformation input
T2	Transformation output
UPC	Universal Product Code
USDA	United States Dept. of Agriculture
WMS	Warehouse Management Systems

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Appendix: Background Information on Regulatory and International Environment for Traceability

This appendix provides a nonexhaustive summary of some of the regulatory initiatives around the world as a reference.

Canada. There are no specific traceability regulations for food commodities in Canada other than for livestock. However, traceability of processed food products is verified through proper packaging and labeling in accordance with the Consumer Packaging and Labelling Act and regulations, and the specific Act and regulations for a food commodity, as well as the Food Safety Enhancement Programs (FSEP) for meat products. For example, traceability of meat and poultry products is monitored and verified through the FSEP under section of its Recall System. It is required that federally regulated processing plants have established Hazard Analysis and Critical Control Points (HACCP) plans and Prerequisite Programs and be able to demonstrate product recall and traceability (F 1.1.1) and product coding and labeling (F 1.1.2) (CFIA, Meat and Meat Products, Chapter 3, 2013).

China. The government of China is gradually establishing and improving national food safety laws and regulations with requirements for food traceability.

On July 2007, Decree No. 503 of the State Council of the People's Republic of China (Special Regulations of the State Council on Strengthening the Supervision and Administration the Safety of Food and Other Products) required that the seller needs to establish an inspection system for the received products, verify the business license of the supplier, and verify the certification of the product and identifier of the product. The seller needs to establish product purchasing ledger to record product name, specification, quantity, supplier's contact information, and time of purchasing. The wholesaler needs to establish product sales ledger to record product variety, specification, quantity, and product flow. The decree also requires the wholesale and sale operators of food establish the purchase and sales ledger and save the ledger at least 2 y, from which the source of food products and sales flow could be identified.

In 2009, "Food Safety Law of PRC" and its implementing regulation were promulgated, in which food producers are required to establish purchase inspection record system and food delivery inspection record system, and accurately record law matters, or retain relevant notes of the purchase or sale. Food safety management of the production process should also be accurately recorded. Operators of food are required to establish records of the source of the products and sales. The retention period of notes and records should be not less than 2 y, so that in the event of food safety problems the relevant products and responsibility can be traced (Liu and others 2012).

On September 16, 2010, The State Council of the People's Republic of China issued a circular entitled "Further Strengthening the Work of Dairy Quality and Safety," to "improve the dairy traceability system" and "implement electronic information traceability system." In the same year, the latest revision of "Review of permit conditions for infant formula milk powder production (2010 edition)" and "Review of permit conditions for dairy production (2010 edition)" (AQSIQ 2010 Notice No. 119), required dairy enterprises to establish an "electronic information traceability system" and standardize the quality control information on key processes or critical control points that need to be recorded (Liu and others 2012).

It is reported that the Chinese Food and Drug Administration (CFDA) will establish the product traceability system nationally in 2014, to allow all the food companies to establish the traceability system. Infant formula milk powder, dairy products, meat, and alcohol (mainly wine) will be the 1st food sectors to implement the system, which will then gradually be extended across the country.

These regulations show that the traceability requirements are mainly required at the trading event; there are no specific requirements for internal data collection. Also, there are no requirements for collection of specific data relating to processing.

European Union. Besides increasing consumer demands, there are many legislative requirements regarding traceability at the EU-level. With regard to these rules the actual legal requirements vary with regard to some aspects, and mostly require a "one-step-forward" "one-step-back" as well as a lot-based traceability. Motivation and scope of these rules cover sustainability and safety aspects as well as food and nonfood products. In this best-practice guidance document, we want to focus on food-related rules.

Regulation (EC) No. 178/2002. Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laid down the general principles and requirements of

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Glossary

Term	Description
Activity Number	A unique identification assigned to a process that influences the traceability of a food. For example, work order number, purchase order number, and invoice number.
ASN	Advance shipment notice
Batch/Lot Number	A batch unites products/items that have undergone the same transformation processes. Batch and Lot are considered synonyms. GS1 Global definition: Reference number assigned by manufacturer to a series of similar goods or seafood under similar conditions.
Consumer item	The trade item intended to be sold to the end customer.
Critical Tracking Event	A point in the supply chain of a food where certain key data elements would need to be captured for the purpose of enabling traceability.
External Traceability	External traceability takes place when components of a traceable item are physically handed over from one trading partner (traceable item source) to another (traceable item recipient).
Fixed-Weight	A term used to denote that a product's weight is constant from case to case or from item to item. It is sometimes known as set weight or fixed measure. A fixed-weight product is typically priced per selling unit rather than per weight.
GTIN® (Global Trade Item Number)	The format in which Global Trade Item Numbers (GTINs) must be represented in a 14-digit reference field (key) in computer files to ensure uniqueness of the identification numbers. GS1 Global definition: A particular Global Trade Item Number, a numerical value used to uniquely identify a trade item. A trade item is any trade item (trade item or service) upon which there is a need to retrieve predefined information that may be planned, priced, ordered, delivered, and/or invoiced at any point in any supply chain.
GS1 System	The specifications, standards, and guidelines administered by GS1.
Identification	The identity assigned to an item or party that is needed to access other relevant information about the item or party.
Internal Process	A series of actions, changes or function(s) within a company or organization that brings about a result.
Internal Traceability	Internal traceability takes place when a trading partner receives one or several components of traceable items as inputs that are subjected to internal processes, before one or several transformed components or finished products of traceable items are shipped out.
Label/Case Markings	A tag, sticker, or printing on product packaging that provides information about the product inside.
Link	Recording the information necessary to establish the relationship to other relevant information.
Location	A place where a traceable item is or could be located [ISO/CD 22519]. A place of production, handling, storage, and/or sale.
Logistic Unit	An item of any composition established for transport and/or storage that needs to be managed through the supply chain.
Master Data	Master Data describe each item and party involved in supply-chain processes. Master data are defined as data having the following characteristics: • Permanent or lasting nature • Relatively static, not being subject to frequent change • Accessed/used by multiple business processes and system applications Can either be neutral or relationship dependant.
Packer	An entity that is responsible for packaging food products into primary and/or secondary containers. This may be done on the field, in a processing facility or independently.
Party	A party or location is any legal, functional, or physical entity involved at any point in any supply chain and upon which there is a need to retrieve predefined information. A party is uniquely identified by a GS1 Global Location Number.
Process	A series of actions or steps toward achieving a particular end. Examples of common processes include Production, Transformation, Quality Control, Storage, Transportation, Movement, Recycle, Return, Packing, Receiving, Traceability, and so on.
Product Description	GS1 Global definition: A piece of information reflecting a characteristic related to an identification number [for example, an expiration date or a product description related to a GTIN].
Quantity	A precise number of articles, pieces, or units. Used in conjunction with Unit of Measure.
Receipt Date	GS1 Global definition: Date/time upon which the goods were received by a given party.
Record	Act of creating a permanent piece of information constituting an account of something that has occurred.
SSCC (Serial Shipping Container Code)	The 18-digit GS1 System Identification Key comprising an extension digit, GS1 Co., Prefix, Serial Reference, and Check Digit used to identify a logistic unit.
Serial Number	A code, numeric or alphanumeric, assigned to an item for its lifetime. A unique individual item may be identified with the combined Global Trade Item Number and Serial Number.
Share	Act of exchanging information about an entity or traceable item with another Trading Partner.
Ship Date	GS1 Global definition: Date on which goods should be shipped or dispatched by the Supplier.
Shipment	An item or group of items delivered to one party's location at one moment in time that have undergone the same dispatch and receipt processes.
Traceability	Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration (GS1, 2009). [ISO 9001:2000] Traceability is the ability to trace the history, application or location of that which is under consideration.
Traceability Data	Any information about the history, application, or location of a traceable item. This may be either Master Data or Transactional Data.
Traceable Item	A physical object where there may be a need to retrieve information about its history, application, or location. The level at which the traceable item is defined within a product packaging or logistical hierarchy is dependent on the industry and degree of control required. Could be tracked, traced, recalled, or withdrawn. Could exist in multiple locations at the same time (for example, if identified at the trade item and batch level). A traceable item may be related to another traceable item. See also definition for process.
Tracing (Tracing Back)	The ability to identify the origin attributes, or history of a particular traceable item located within the supply chain by reference to records held. "Tracking back" and "tracking forward" are the preferred terms used in this document.
Tracking (Tracking Forward)	The ability to follow the path of a traceable item through the supply chain as it moves between parties.
Trade Item	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in any supply chain.
Trading Partner	Any supply-chain partner that has a direct impact on the flow of goods through the supply chain. Examples include 3rd-party logistics provider, manufacturers, retailers, wholesalers, distributors, or operators, and growers.
Transformation	A change to the nature of a traceable item that changes the identity and/or the characteristics of the traceable item. The act of changing the item such as combining ingredients to make a finished product or case picking to create a new pallet. Transformation can be production, aggregation, grouping, splitting, mixing, packing, and repacking traceable items.
Transporter	The party that handles and or stores the traceable item from one point to another without transforming the item. Receives, carries, and delivers one or more traceable items. The Transporter may only have "possession, custody, control" of a traceable item, as distinct from ownership.
Unit of Measure	The unit of measure relating to a specific quantity.
Variable-Weight	A term used to denote that a product's weight varies from case to case or from item to item. It is sometimes known as random weight, catch weight, or variable measure. A variable-weight product is typically priced on the true weight of the item rather than per selling unit.

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food law, establishing the European Food Safety Authority and laid down procedures in matters of food safety. It requires food business operators (FBOs): (1) to be able to identify from whom and to whom a product has been sold; (2) to have systems and procedures in place that allow for this information to be made available to the Competent Authorities upon request. The requirement relies on the "one-step-back" "one-step-forward" approach which applies to FBOs.

Article 18 does not specify what type of information should be kept by the food and feed business operators. However, to fulfill the objective of Article 18, the following information should be kept for at least2 y:

- Name, address of supplier, and identification of products supplied;
- Name, address of customer, and identification of products delivered;
- Date and, where necessary, time of transaction/delivery;
- Volume, where appropriate, or quantity.

Article 18 does not specify a minimum period of time for keeping records; therefore it is for the businesses to decide, bearing in mind that failure to produce adequate records would constitute an offence.

Article 18 does not require internal traceability (that is, the matching up of all inputs to outputs). Nor is there any requirement for records to be kept identifying how batches are split and combined within a business to create particular products or new batches.

Food retailers are not required to keep records of sales to the final consumer (since consumers are not food businesses). Wholesalers supplying to retail outlets are required to keep records. In the instances that a retailer knows that it is supplying to another food business, for example a catering outlet, traceability requirements should be adhered to. Caterers such as restaurants will need to keep traceability records of inputs, but will not be required to keep records of supplies to the final consumer (GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 14, 17, 18, 19, 2002)

The general principles for traceability established in Article 18 of Regulation (EC) No. 178/2002 require that the traceability of food be established at all stages of production, processing, and distribution. However, since then many other regulations have been implemented. The main regulations pertaining to food traceability are presented below.

Fisheries and aquaculture: (EU) Regulation 1224/2009 and (EG) 404/2011. The (EU) Regulation 1224/2009 establishing a community control system for ensuring compliance with the rules of the common fisheries policy applies to all fisheries and aquaculture products. This regulation stipulates that lots of fisheries and aquaculture products shall be traceable at all stages of production, processing, and distribution, from catching or harvesting to retail stage. Member States shall ensure that operators have in place systems and procedures to identify any operator from whom they have been sold with lots of fisheries and aquaculture products and to whom these products have been supplied. Lots can be formed from different consignments of fish, but traceability back to production identification unit must be maintained. The traceability and information requirements shall be affixed by way of an identification tool from January 2013 to fisheries subject to a multiannual plan; and as from 1 January 2015, to other fisheries and aquaculture products. The traceability, respectively, labeling and information requirements for all lots of fisheries and aquaculture products shall include: Lot identification; identification number of aquaculture unit or fishing vessel; FAO alpha-3 code of each species; date of catch or production; quantity; name and address of supplier; commercial designation; scientific name; geographical area and production method; whether previously frozen. Regulation (EU) No. 404/2011 of 2011 lays down detailed rules for the implementation of regulation (EC) No. 1224/2009 establishing a community control system for ensuring compliance with the rules of the Common Fisheries Policy.

Food of Animal Origin: (EU) Regulation 931/2011. Commission Implementation Regulation (EU) No. 931/2011 establishes provisions implementing the traceability requirements of Regulation (EC) No. 178/2002 for FBOs with respect to food of animal origin. This legislation states that certain specific traceability information must be made available to the receiving FBO.

The regulation is effective beginning July 1, 2012, and places an obligation on FBOs to ensure that the following information concerning consignments of food of animal origin is made available to the FBO to whom the food is supplied and, upon request, to the competent authority: an accurate description of the food; the volume or quantity of the food; the name and address of the premise from where the food has been dispatched; the name and address of the seller; the name and address of the premise where the food is to be delivered; the name and address of the buyer; a reference identifying the lot, batch, or consignment, as appropriate; and the date of dispatch.

The information including intake and dispatch records must be updated on a daily basis, and as a minimum be kept until it can be reasonably assumed that the food has been consumed.

Beef labelling: (EU) Regulation 1760/2000. In 2000, the European Commission introduced Regulation 1760/2000, applicable since September 1, to ensure that all beef producers label their product with the following information: country of birth, country or countries of fattening, country of slaughter, country or countries of cutting, approval number of slaughterhouse and cutting premises.

The aim of the legislation was to ensure that beef in retail outlets could be linked back to the individual animal or the group of animals from which it originated. The BSE crisis of the 1990s caused a decline in beef consumption across Europe and the Commission hoped that with the introduction of this legislation, consumers would regain confidence in beef. The system for identification and registration of animals must be computerized, and there must be individual registers for each holding. Each animal must be identifiable individually with an ear tag and have a passport to trace their movement.

Origin labeling of meat of swine, sheep, goats, and poultry: (EU) Regulation 1337/2013. The EU Regulation 1337/2013, applicable beginning April 1, 2015, sets out the labeling modalities required indicating the country of origin or place of provenance for fresh, chilled, and frozen meat of swine, sheep, goats, and poultry.

The regulation stipulates that food business operators, at each stage of production and distribution, shall have in place and use an identification and registration system. This system should ensure a link between the meat and the animal or group of animals from which it was obtained; which at the slaughter stage is the responsibility of the slaughterhouse.

That system shall be applied in such a way as to ensure: (a) the link; and (b) the transmission of the information relating to the

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country of rearing, country of slaughter, batch identifying code, as appropriate, together with the meat, to the operators at the subsequent stages of production and distribution.

Each food business operator shall be responsible for the application of the identification and registration system within the stage of production and distribution at which it operates. The food business operator who packs or labels the meat shall ensure the correlation between the batch code identifying the meat supplied and the relevant batch or batches of meat from which the labeled batch or pack is constituted.

Genetically modified organism (GMO): (EU) Regulation 1830/2003. Applicable since April 18, 2004, this regulation concerns the traceability and labeling of GMOs and the traceability of food and feed products produced from GMOs. Combined with Regulation (EC) No. 1829/2003, these regulations constitute the legal regime relating to the authorization, labeling, and traceability of genetically modified food and feed.

At the 1st stage of placing on the market the aforementioned products, operators must ensure that the following information is transmitted in writing to the operator receiving the product: (a) that they contain or consist of GMOs; and (b) that the unique identifier(s) assigned to those GMOs is in accordance with labeling requirements set out in the regulation.

Food contact material: (EU) Regulation 1935/2004. Applicable beginning October 27, 2006, this regulation relates to materials and articles intended to come into contact directly or indirectly with food, in order to secure a high level of protection of human health and the interests of consumers.

The regulation stipulates that traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information, and the attribution of responsibility. Business operators must have in place systems and procedures to allow identification of the businesses from which and to which materials and articles were supplied. That information shall be made available to the competent authorities on demand.

Japan. The Japanese Ministry of Agriculture, Fishery and Foresty (MAFF) has mandates under its Beef Traceability program for domestic beef, requiring that an assigned number is carried through from the birth of the cattle, the processed carcass at the abattoir, and the label on the final packaged product, or its invoice. With this assigned identification number, a consumer can access the system online and review the history of the beef products that they purchase (MAFF). The Rice Law enacted in 2009 requires recordkeeping of transactions of rice and grains, and must inform consumers and business partners of origin information, to allow prompt identification of the distribution route when a problem occurs.

Other than the beef and rice products, there are no other regulations requiring food-product traceability. The Japanese Handbook for Introduction of Food Traceability Systems (2007) provides comprehensive guidance for food standards, in accordance with Japanese Agricultural Standards (JAS) and traceability requirements. This handbook is the primary reference for producers and food business operators, and provides the basic framework and core information for writing guidance documents for specific food products and food industries. Several traceability guidance documents have been published, for fresh produce, eggs, shellfish (oyster and scallop), farmed fish, and laver (seaweed). Guides for other food products are in development.

United States. The Bioterrorism Act of 2002 (BT Act), and the recordkeeping requirements contained in the Act, represented a major step forward in the implementation of a product tracing system for Food and Drug Administration (FDA)-regulated food products. This Act requires a paper trail documenting food distribution, to allow determination of the source of contamination in the event of a foodborne illness outbreak.

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

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

Records are required for food received and released, and must include: previous/subsequent source (including full contact details), description of food (brand name and variety), date received/released, lot or code number (if relevant), and quantity and packaging. When food is released, records additionally must include information "reasonably available," identifying specific sources of each ingredient to each lot of finished product. In cases where food processors commingle ingredients, such as flour from different suppliers, FDA accepts that manufacturers may not be able to identify one specific source (McEntire 2010).

Section 204 of the Food Safety Modernization Act requires the U.S. FDA to develop additional recordkeeping requirements for high-risk food to improve their traceability. These mandates are yet to be published and are expected to be available in draft format during the year 2014.

Appendix: International Standards and Guidance in Different Countries

China

Working with stakeholders in the different food sectors, 2 government agencies in China have published several national standards for specific food products since 2009.

National standards on traceability requirement. On December 31, 2012, the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) published GB/T 29373-2012, known as the national standard "Traceability requirement for agricultural products – Fruits and vegetables." Following publication of this standard, a national standard on fish and fishery products—GB/T 29568-2013—was published on July 19, 2013. These standards establish the requirements for traceability system development and record collection in these 2 sectors.

The standards require data collection in 3 areas: received data (data received from the upward supplier), processed data (data in the processing facility), and output data (data provided to the downward supplier chain).

All stakeholders in the supply chain are required to collect both the received data and output data if sending or receiving a traceability unit; and processing stakeholders are required to collect the

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processed data. There are 2 types of data: basic traceability data and expanded traceability data. The basic traceability data involve the product traceability information (that is, Key Data Elements [KDEs] for traceability). The expanded traceability data involve other related information about the specific supplier, product, and trading information, and also other information.

Traceability data collection is separated as external data collection and internal data collection. When a traceability unit is transferred from one stakeholder to another stakeholder, external data—including the received data and output data—are generated and need to be captured. If a traceability unit is only transferred in the different departments in the same facility, the data collected are internal data as processed data.

Agricultural industry standard on traceability requirement. During 2009 to 2011, the Ministry of Agriculture (MOA) of the People's Republic of China published 7 agricultural industry standards:

(1) Operating rules for quality and safety traceability of agricultural products—guideline, April 23, 2009
(2) Operating rules for quality and safety traceability of agricultural products—Fruit, April 23, 2009
(3) Operating rules for quality and safety traceability of agricultural products—Livestock meat, April 23, 2009
(4) Operating rules for quality and safety traceability of agricultural products—Tea, April 23, 2009
(5) Operating rules for quality and safety traceability of agricultural products—Cereal, April 23, 2009
(6) Operating rules for quality and safety traceability of agricultural products—Vegetable, September 1, 2011
(7) Operating rules for quality and safety traceability of agricultural products—Wheat Flour and Noodle, September 1, 2011

The standards stipulate the traceability term and definition, requirement, data collection, data management, coding method, traceability identifier, system operation self-inspection, and management of quality and safety issues. As for the data collection, there are specific data required at different Critical Tracking Events (CTEs).

Both the national and industry standards serve as recommended guidance for the industry sectors. The standards were based on stakeholder discussion, and were written by either the assigned research bureau or the research institution. These standards are not regulation *per se*, but serve as guidance for the industry in implementing the traceability system in their facilities. The standards could be enforced as regulation if the China Food and Drug Administration (CFDA) chose the standards as the requirement for the purpose of traceability. The state-owned facilities, which are managed under the MOA, have been recommended to implement these standards in their facility.

The national standard has a structure that is similar to the Global Food Traceability Center (GFTC) framework, which recognizes the input and output for the transportation event. Also, the system has clear requirements for basic traceability data and expanded traceability data. The basic traceability data are similar to the KDEs in the current framework. The agricultural standard does not separate the data as required KDEs and linked KDEs; instead, all the data are collected as requested. The required KDEs are all collected, as for the current framework's requirements for certain CTEs. The agricultural standard also requires the facility to generate a traceability code which links to the barcode. Through this practice, consumers can scan the 2-dimensional codes in the supermarket to obtain the traceability information such as production date, lot number, origin of production, producer name, and so on, or acquire the product traceability information on line, using the barcode of the products.

Japan. The Japanese Handbook for Introduction of Food Traceability Systems, a reference document published in 2007 by the MAFF, provides comprehensive guidance for food standards in accordance with JAS and traceability requirements. The information that is recommended for collection in the traceability system is shown below. The indispensable information collects product name, receiving date, supplier, ID, and quality/weight at the receiving CTE. At the process step, the process record collection includes semi-finished products, as an intermediate step. Raw material ID and quanity/weight are collected as input, then semi-finished product ID and quantity/weight are collected as output; this output also serves as input for subsequent processing, to generate the final product. The product's ID, quantity, and weight are collected as output for this processing step. The manufacture date is also recorded. In the following shipping process, product name, shipping date, buyer ID, and quanity/weight are all collected. Additional information is also collected, such as: processing history of hygiene at the receiving time, quality mangement condition, and so on; processing history of hygiene, quality mangement condition, and so on at each operator's operation; and processing history of hygiene at the shipping time, quality mangement condition, and so on. The handbook also provides definition of lot and recommends the link to be estabished between product and information.

United States. Several industry initiatives have been developed in the United States, and guidance documents have been published.

In 2010, the Produce Traceability Initiative (PTI) published "Traceability for Fresh Fruits and Vegetables Implementation Guide," which facilitates implementation of GS1 traceability standards in the produce industry supply chain. The primary supply-chain partners are grower, packer/repacker, distributor/trader, retail store, and food service operator.

In addition to this document, others are available. The Guidance for Dairy Product Enhanced Traceability was published in 2013 (US Dairy Traceability 2013). This guidance is the product of a year-long pilot study of 6 processors that benchmarked and created recommendations for the requirements of voluntary enhanced traceability best practices that are tailored to customer and processor needs. Traceability for Dairy, Deli, & Bakery U.S. Implantation Guide (Intl. Dairy Foods Assn., Intl. Dairy-Deli-Bakery Assn., and GS1) was published in 2013 (GS1US 2013).

Traceability for meat and poultry: US implementation guide, developed by 6 national meat associations along with GS1 was published in 2010 (mpXML 2010). The scope of this guideline establishes both minimal requirements and best practices, to share information between trading partners. The guide addresses: (1) traceability practices from the supplier's processing facility to the point of consumer sale; (2) all meat and poultry products for human consumption; (3) all levels of product hierarchy, including pallets, cases, and consumer items; and (4) U.S supply-chain segments including suppliers, wholesalers, distributors, and retailers.

One guidance document which particularly focuses on CTEs was published in 2010. The mpXML guide provides detailed examples of information capture for events common to each supply-chain segment, and illustrates how CTE methodology

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could be adapted to fit industry practices (such as in-store product transformation and direct-store-delivery of products) (mpXML 2010).

U.S. Seafood Implementation Guide (Natl. Fisheries Inst. and GS1) was published in 2011 (NFI 2011). Each of these guidance documents is based on use of GS1 global standards for supply-chain management and product identification. The Guide was developed in collaboration between NFI, GS1 US, and U.S. seafood industry stakeholders to provide consistent, practical seafood-traceability voluntary guidance for industry-wide use. It defines minimum requirements and best-practice recommendations for tracking seafood as they move through the supply chain from farms to processors, suppliers, distributors, retailers, and food service operators.

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