



Figure 1—Stakeholders in the bakery sector supply chain.

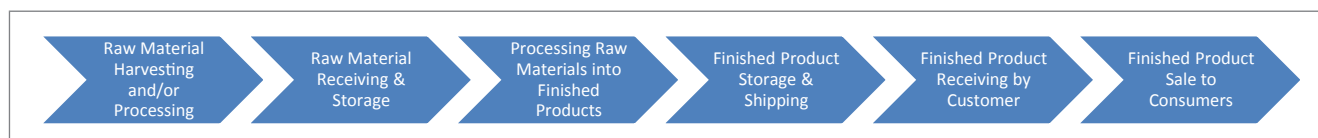


Figure 2—A simplified process flow diagram for the bakery sector.

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.

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-