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# Product Tracing in Food Systems

## *Executive Summary*

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

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

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

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

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

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

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

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

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

## **Recommendations**

### **Required Key Data Elements**

Upon request during a traceback investigation, the following data elements should be made available to the FDA by the applicable supply chain partners (from farm to the retail/foodservice outlet). The nature of the key data elements is such that linkages are maintained, allowing a product to be traced through the supply chain. For example, each time a lot number is changed, the original and resulting lot numbers must be recorded. Similarly, if a lot number is unchanged, but the product moves between facilities, this information must be recorded so that the path of the product can be followed. The key data elements that should be provided in an electronic form using an approved standardized format, for each case containing a product of interest include:

- Physical location that last handled the product, whether the manufacturer or not, and, if applicable, contact information for the broker who handled the transaction

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

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

#### 1. **Recordkeeping**

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

#### ***Internal Product Tracing***

The ability to trace products internally accurately must be maintained by food companies. For products that do not undergo further processing or transformation (e.g., the case is not opened) a one-to-one relationship between incoming and outgoing lots must be maintained. For example, if a pallet contains cases with different lot numbers, those cases will need to be followed individually through a system. Incoming lot numbers are one of the key data elements that need to be captured and made available to FDA in an electronic form within 24 hours of an official request. From a practical standpoint, recording each lot number of each case may require additional labor and slow operations. Since this information should also be printed on paperwork that accompanies or is related to the product, examining lot numbers in a pallet should be done as verification. Mechanisms exist whereby a pallet label can readily communicate the information for each case without the need to record information

from every case. If a pallet comprised of cases with different lot numbers is divided into individual cases, simply providing the various locations that received cases from the pallet (e.g., the recipients), without indicating which lot was shipped to each location, results in a loss in the ability to trace product. In the case of a mixed pallet, shipping records must show where the cases were sent according to the lot number on the case. Lot numbers should also appear on the invoice, bill of lading and/or purchase order or other accompanying or related paperwork.

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

## **2. Approved Standardized Formats**

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

## **3. Electronic vs. Paper**

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

## **4. Required Audit**

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

## **5. Training**

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

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## **Core Recommendations**

Each supply chain partner must:

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

Standardized ways of expressing key data elements should be agreed upon

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

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## **Background**

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