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What systems you need and what to expect from a traceability audit

Food manufacturers are required by regulatory agencies and most audit standards to establish procedures and maintain records to document the traceability of the products they produce, the ingredients they contain and the materials in which the products are packaged. While the specific requirements of these agencies and standards may vary slightly, they share the goal of facilitating the traceability of contaminated foods and ingredients in the event of a product recall. They also help build consumer confidence in product transparency through demonstrated label claims like organic, non-GMO and source of origin. Strong traceability programs also help prevent food fraud by regulating all aspects of an increasingly global supply chain.

This article discusses the current state of traceability and product recalls, the effects of regulation and voluntary industry standards on traceability, what to expect from a traceability audit and what systems ensure traceability.

Traceability today

Traceability is the ability to track any food through all stages of production, processing and distribution (including importation and at retail). It is a risk-management tool that also allows food business operators or authorities to withdraw or recall products which have been identified as unsafe. It is a cornerstone of the EU's food safety policy¹.

In the UK, the most common cause of food recalls in 2014 was microbiological contamination, at 24% (that includes *E. coli* at 10%,

Salmonella at 4% and *Listeria* at 3%). Allergens accounted for 8% of all recalls². In the EU from January through August 2015, 14% of food alerts were caused by allergens and 37% were due to pathogenic microorganisms (which includes *Salmonella* at 19%, *Listeria* at 9% and *E. coli* at 4%)³. In the U.S. between 8 September 2012 and 7 September 2015, the most common cause of food recalls was undeclared allergens, which accounted for 43.6% of all recalls. The next most common reason for a recall was contamination with *Salmonella* at 28.7%, followed by contamination with *Listeria monocytogenes* at 17.3%⁴.

Despite the progress the food industry is making in improving equipment and building design, process controls and management systems, product recalls are still a fact of life in the food business. There are several reasons for this. Food companies and distribution

systems are becoming increasingly larger, more consolidated and globalised and supply chains are increasingly complex. Although this in itself does not necessarily increase the risk of the occurrence of contaminated foods, it increases the number of points at which food could be contaminated and increases the number of people or other food manufacturers who may receive a contaminated product. For example, a contaminated basic raw ingredient such as a spice may be distributed all around the globe and be used by many other food manufacturers, triggering multiple finished product recalls.

Another factor that has increased recalls is the improved capabilities of health investigators and epidemiologists to properly attribute pathogens to a single source. National or regional information sharing systems (such as PulseNet) allow investigators to accurately match pulse field gel electrophoresis patterns and whole genome sequencing data. With this information, investigators can determine if a pathogen found to be the source of a foodborne illness in one area matches pathogens found in other illnesses in other areas. Other information systems for sharing and tracking foodborne illness include the Rapid Alert System for Food and Feed in the EU and the Food Alert System in the UK. By conducting food history interviews with the affected people, investigators can establish common food sources, eventually identifying a single source or ingredient responsible for the outbreak.

Regulation and voluntary standards aid traceability

Because of the cascading effect of illness and recalls, it is essential that manufacturers be able to trace their ingredients, products and packaging materials forward and backward. Regulatory and third-party audit standards (such as SQF, BRC, ISO 22000 and IFS) require food manufacturers to maintain traceability one step forward into distribution, and one step back toward the source of the ingredients. Manufacturers must establish systems for keeping records that will link ingredients and packaging to the products in which they are used and to the recipients of those products. **Figure 1** (page 68) illustrates how a raw material or ingredient is tracked from being received to being distributed. In order to achieve this, a manufacturer utilises systems to record specific information about raw materials, packaging materials and finished products.

What to expect in a traceability audit

In a typical audit, an auditor may use a technique called a vertical trace. The auditor will select a product with a unique lot number produced on a particular day. He or she will ask the manufacturer to produce all of the records related to the production of that lot of product, including production batch sheets, receiving records for the ingredients and packaging used in the lot, records of any rework or overrun added to the product or created by it, and inventory and distribution records of the lot. This allows the auditor to verify that the manufacturer documents the source, usage and distribution of materials and packaging according to its established procedures. Those records must link the unique identifiers of the raw materials to the identifier assigned to the finished product.

There are a variety of commercially available software systems designed to assist food manufacturers in documenting the identity of materials as they flow through the process of receiving, storage, production and distribution. They have the added benefit of assisting the



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manufacturer in the production of identity preserved products such as organic, non-GMO and kosher products. They may also assist in inventory control and inventory rotation. Some of these systems are very complex and the initial implementation can be a daunting task. These may not be suitable for smaller manufacturers.

Traceability exercises

In many audit standards, the manufacturer will be required to perform a traceability exercise during the audit. This is similar to a vertical trace performed by an auditor, but it places the burden of demonstrating an established traceability system on the manufacturer. The supplier will be



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Figure 1: Raw material tracking from receipt to distribution

required to demonstrate that it can account for the whereabouts of all of a particular product, ingredient or packaging material through a mass balance exercise.

In an onsite traceability exercise, the auditor will select a finished product, and the supplier will be required to produce records of the disposition of the product and the source of the ingredients and packaging used to produce it.

The manufacturer should be able to account for all, or nearly all, of the lot in question. In addition to accounting for all of the finished product, a supplier should also be able to produce documentation of products or ingredients that don't end up in normal distribution channels. This could include raw materials or finished products removed for testing of raw materials, work in process or finished products, and promotional samples. The manufacturer should also be able to estimate or document normal amounts of loss it experiences through spillage or culling. The manufacturer's records should also indicate occurrences which result in extraordinary product loss, such as might occur when a product is processed to completion without a key ingredient. The purpose of the mass balance exercise is to demonstrate that the supplier can account for all of a lot of product, ingredient or packaging material, which is especially critical in the event that a lot has been determined to be contaminated or mislabelled.

The ability to trace forward is required when a manufacturer discovers that it has packaged a product using an incorrect label. This could happen when a worker uses the wrong ingredient when

formulating a batch. It could also occur when a manufacturer changes an ingredient supplier and fails to notice that the ingredient does not contain the same sub-ingredients as the ingredient it replaced. In addition, incorrect labelling could occur if a worker selected the wrong label, container or packaging material for a product, or if the manufacturer is informed by its supplier that the ingredient it delivered was mislabelled.

Correct labelling is especially crucial when the product contains one or more allergens. The manufacturer must have allergen management systems in place to assure that allergens are excluded from products in which they should be absent. Therefore, the manufacturer must have robust systems to assure that the correct ingredients are used in its formulations, and that labels are correct and properly applied. In the event of mislabelling, the manufacturer must be able to trace the ingredients forward to issue a recall or public health alert that informs the public of specific affected products.

Allergen labelling requirements vary from country to country. The U.S. Food and Drug Agency has identified eight major allergens, Canada has identified 11 and the European Union has identified 14 foods and chemicals that fall under its allergen labelling requirements. Each country has specific requirements for labelling allergens. It is incumbent on the food manufacturer to comply with the labelling requirements in the country where the product is to be sold.

The manufacturer must be able to identify every recipient or the location of any mislabelled product in its own facility. Receiving records

such as bills of lading with lot codes or another unique identifier will establish the identity of products received. Raw material warehouse storage records with the same unique identifier will establish the location of the product in the warehouse. Warehouse 'pick' records will document the removal from the warehouse and delivery to the batching and/or production areas. Batch records, if properly created, will document the use of ingredients in each lot of finished product. Each of these records establishes a traceable link to the previous production step. The manufacturer can create a stronger record of the packaging used by saving a physical sample of the label or by taking a picture of the label or package used.

Bulk ingredients such as flour and oil also present a unique traceability challenge for food manufacturers. In large processing facilities, these ingredients are often received into storage silos or tanks without a clear designation of (or break between) lots. Using gravity, they are filled from the top and emptied from the bottom. These storage facilities may be emptied and cleaned infrequently, making it impossible to prove if or when a contaminant had been used and when it was no longer present in the tank or silo.

Manufacturers who use bulk ingredients without establishing verifiable breaks between lots will have larger amounts of product at risk of being recalled and will have more difficulty in tracing a product or ingredient. In the event of a recall, it is likely that the agency with regulatory authority over the manufacturer will insist that all products produced from the time the contaminated ingredient was initially used until a break occurred be recalled.

Traceability documentation

Audit standards require manufacturers to conduct tests of their traceability and recall systems at least once per year. Audit standards specify an acceptable time allowed to conduct the exercise, usually between two and four hours. A manufacturer's traceability program should document the acceptable range for the accountability of product used in the exercise. The documentation for a traceability test should include the following:

- Ingredients used including quantities and unique identifier
- Packaging used including quantities and unique identifier

- Finished product lot identification and quantity produced
- Quantities of waste produced
- Location and quantities of product within the manufacturer's control and quantities shipped to individual recipients
- Start and finish time of the exercise

In addition to supply chain management, traceability is also important in monitoring and calibrating production and laboratory equipment to ensure food safety and regulatory compliance. To make sure the equipment performs accurately, and that the test methods used are valid, they must be calibrated to national or international standards, such as NIST, ISO 17025 or AOAC.

In conclusion, not only is traceability required by regulatory agencies and third-party audit standards, but it is a key component of risk management and the control of food safety and quality. Having a robust, documented system to ensure traceability assists companies in meeting regulatory or certification standards for food safety and helps to quickly identify and recall affected products in the event of contamination. 🗑️

About the Author



Michael Govro is a food safety, quality and public health professional with over 35 years of experience in private industry and regulatory agencies. His experience includes state and federal inspections, third-party food safety, food quality and food defence auditing, emergency preparedness, epidemiological investigations and program management. He previously served as the Assistant Administrator of the Food Safety Division of the Oregon Department of Agriculture.

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