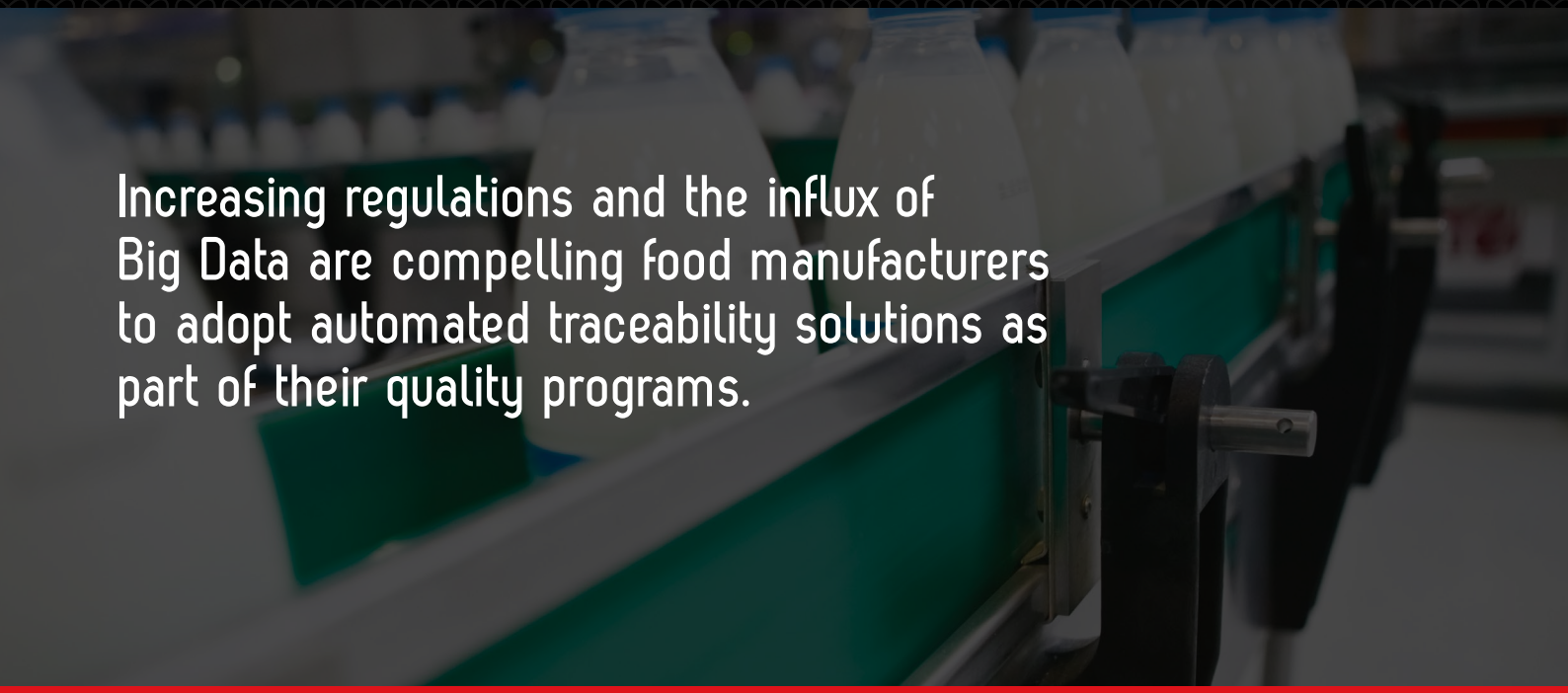
Whitepaper

InfinityQS®
Quality Re-imagined

Food Traceability Best Practices in the Age of Big Data



Increasing regulations and the influx of Big Data are compelling food manufacturers to adopt automated traceability solutions as part of their quality programs.

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"Preventing problems before they cause harm is not only common sense, it is the key to food safety in the 21st century."

Dr. Margaret Hamburg
Commissioner of the FDA

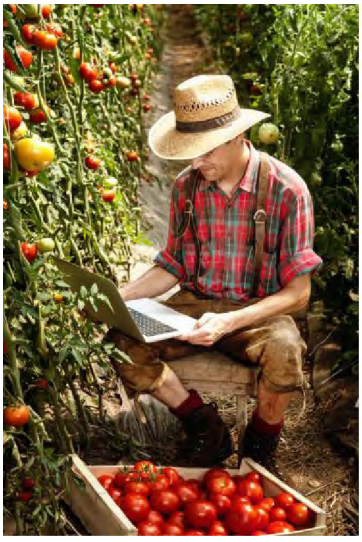
Dealing with the Deluge

Failures in the rules and processes that protect the U.S. food supply have led to numerous high-volume, high-visibility recalls over the last 10 years. Such recalls are financially damaging. The economic costs of food products recalled from January 2011 to September 2012 alone were over $227 million. Recalls also harm company reputations, sometimes irreversibly. Companies such as Peanut Corp. of America have been unable to recover from such incidents and ultimately declared bankruptcy.

Events like the horsemeat scandal in Europe have generated increased attention on a lack of supplier oversight as well. Ensuring safety and integrity in the food supply is no longer just an issue of what happens inside the manufacturer's walls. In 2012, a provision of the Food Safety Modernization Act went into effect, requiring that all players in the country's food supply chain be able to quickly trace from whom they received a food product and to whom it was sent.

The new traceability provisions also require food manufacturers to maintain information in digital form. Although the move to computer-based tracking may help the FDA trace problems back to their sources more quickly and accurately, it also creates a deluge of data for food manufacturers to manage. This white paper examines the increasingly demanding traceability requirements and explores how food manufacturers can meet the requirements efficiently and effectively as part of their ongoing quality management programs.

Prevention is the Best Medicine



According to the United States Public Interest Research Group, 48 million people get sick from eating tainted food each year[1]. Once reports of a foodborne illness surface, the faster the source can be found and a recall issued, the better the chances of preventing further outbreak.

Unfortunately, the FDA has had difficulty quickly pinpointing the sources of foodborne illness outbreaks. A lengthy food supply chain, in which a product might change hands five times from farm to fork, complicates the process, as do the challenges growers, distributors, wholesalers, and retailers face with record-keeping.

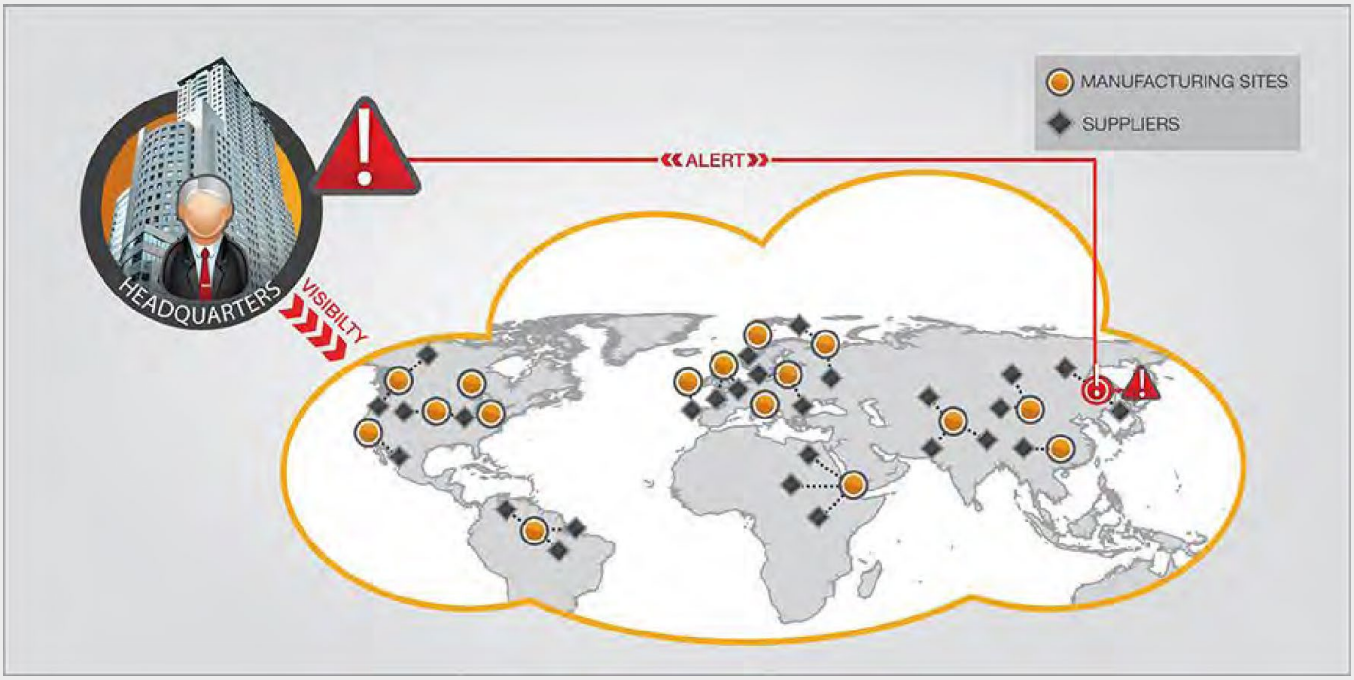
[1] **United States Public Interest Research Group http://www.uspirg.org/reports/usp/total-food-recall**

The inability to pinpoint the source of an outbreak quickly can increase the number of people affected by a foodborne illness. In addition, it can significantly affect innocent growers, distributors, or manufacturers. For example, a national outbreak of salmonella in 2008 sickened more than 1,300 people across the country. Initially, officials identified tomatoes as the source. But over a month later, the correct source was identified as peppers from Mexico. Unfortunately, the damage to the tomato industry was already done – the cost to tomato growers in Florida alone was estimated at $100 million.

Fortunately, improvements are possible. In a report on food traceability released in March 2013, the FDA predicted that improved product tracing "has the potential to reduce the public health impact by up to a total 55% and reduce the economic impact by up to $14 million per outbreak."[2] The report also suggests that a company that improves its ability to trace products can expect to achieve improved business processes, increased supply chain confidence and potential market expansion.

Best Practices in Food Traceability

To meet the FDA's growing recordkeeping and lot-tracking requirements, all food processors must be able to track and trace products across the entire lifecycle, from source to finished product. To do so, up-front controls are critical to identify and stop problems as early as possible. The challenge is how to track and manage the data. Rather than using manual processes that are primarily reactive, food manufacturers that employ technology, such as Software as a Service (SaaS)-based quality management software, can automate traceability, allowing them to rapidly and proactively identify and track every ingredient in their products through processing, packaging, and shipping to the customer location.



[2] Pilot Projects for Improving Product Tracing along the Food Supply System, Institute of Food Technologists, http://www.ift.org/knowledge-center/focus-areas/food-safety-anddefense/~/media/Knowledge%20Center/Focus%20Areas/Traceability/IFT_FDA_ProductTracingPilotsFinalReport.pdf

To accomplish compliance with the FDA requirements, manufacturers need end-to-end visibility, which should come from their centralized quality hubs. Whether organizations are looking to achieve quality on a global scale or gain visibility into the product lifecycle, the Manufacturing Intelligence provided by a quality hub gives manufacturers the power to identify areas for improvement, improve quality, and increase profitability. Without this visibility, manufacturers are at risk for compromising product quality brand integrity and overall process efficiencies, especially during a recall.

The quality hub model requires tagging all data with an enforced universal data description. At a minimum, all shop floor data includes the part, the test name, and the process (or operation) that produced that test. These part, test, and process names need to follow a universal naming convention. Real-time access and traceability become a reality with universal naming convention standards at multiple sites and suppliers. Each data value is tagged with a company, site, part, test, process, time stamp, the name of the person who entered the data and any other necessary descriptive information – all of which is instantly available for both live and historical analysis.

The robust analytical capabilities of a quality hub allow users to slice and dice data in countless dimensions, such as by line, product, geographic region, and even supplier. Enterprise dashboards and reports — accessible via laptop, smartphone, or tablet— allow high-level executive views into quality performance. A quality hub also allows users to interact with data, thus delivering insight to other parts of the organization. Ideally, data is accessible from virtually anywhere, at any time, extending Manufacturing Intelligence beyond the four walls.

Further, lot genealogy reports provide a complete view of the incoming/outgoing product relationship, complete with statistical summary information, allowing organizations to track raw material lot codes throughout manufacturing operations.

For investigation purposes, genealogical “trees” can be created. These reports allow the company to determine:

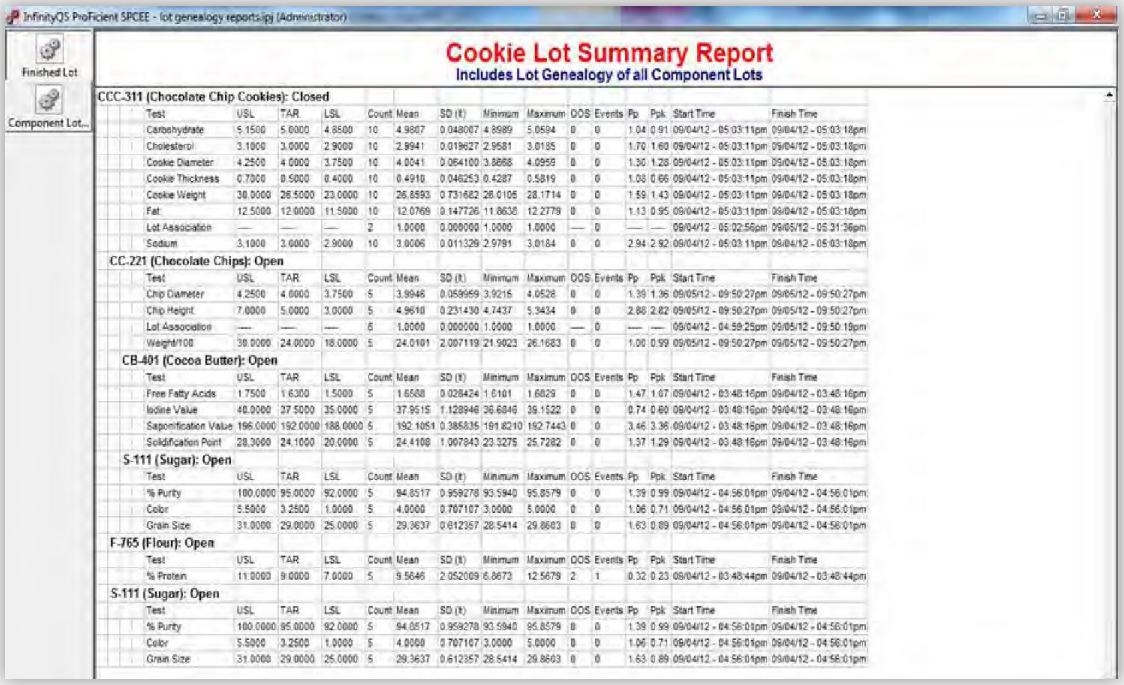
› Materials used in the production of a certain finished lot

› Where incoming raw materials were consumed

› Root causes of non-conforming lots

› Information critical to responding to product recalls

› Which final lots were created from incoming lots



Lot Genealogy allows you to view summary statistics of final products by lot. For a deeper view, you can also look at the component lots and their summary statistics for a complete summary of your product.

An automated traceability approach can also benefit a manufacturer when suppliers change. A company may have an internal tracking system, but how does it ensure separate tracking of each input from each supplier? And how can it prevent comingling of products from different suppliers? Using the traceability functionality in quality management software, raw ingredients, batches, and processes are uniquely identified and tracked using barcodes and highly precise management processes. Timestamps can track a supplier change by hour to narrow down where and when a problem developed.

Cloud-based quality management software also allows data from suppliers to feed into the manufacturer’s quality hub to make real-time traceability data accessible using preconfigured reports. This approach can speed up the entire process as well as identify problems earlier. Rather than waiting for a product to arrive at the manufacturing location, for example, the manufacturer can check it before it leaves the suppliers’ facility and work with the supplier immediately to correct any issues.

Traceability not only helps improve food safety, but also allows companies to hold their suppliers and copackers accountable by assuring they move food products quickly to avoid spoilage.

Automated Traceability in Action

One of North America's largest suppliers of value-added fresh produce recently adopted a cloud solution for its quality management needs. Initially, the company wanted to fine tune processes to ensure its products complied with net weight requirements. Because produce is not uniform, the weight of each package varies. If a product does not meet the minimum net weight requirement stated on the package, the FDA can impose significant fines. But if the company goes over the stated weight, it is essentially giving product away. It is therefore in the company's best interest to tune processes to fill as close as possible to the stated weight.

The produce supplier previously had each of its 10 facilities managing product and process data in separate servers and databases. Company executives wanted a more comprehensive view of data from all facilities to ensure they were meeting net weight requirements and to minimize incidents in which minimum weight significantly exceeded net targets. The company implemented a cloud-based quality management solution that combines data from all 10 facilities into a single cloud database for analysis. The solution does not require a complex IT infrastructure and provides global access with a simple online login.

The software platform also provides dynamic sampling to ensure that quality tests that must be performed at certain time intervals during the process occur correctly and on time. If a regular test raises an issue, the system sends email alerts to key personnel and automates a process state change, so personnel can take corrective action and avoid continuous production of defective product.

The software also helps the company monitor its suppliers. In January 2013, the FDA introduced a rule applicable only to foods consumed raw, such as berries and salad greens, which required stricter standards for growing, harvesting, packing, and holding fruits and vegetables. The rule would increase vigilance for sanitation during irrigation and washing of produce, worker hygiene, cleanliness of materials used in growing soils such as fertilizers and manure, management of animals that could enter crop fields and contribute contamination, and sanitation of processing equipment.

Using the cloud-based quality management hub, the company can visit a farm where it is sourcing lettuce, for example, and perform checks using a mobile device to ensure FDA regulations are met. The data is pushed into the global repository where it is available for audits. In the case of a problem, an email alert is generated automatically to inform personnel that they must enact changes in order to comply with the regulations.

Visualize Your Supply Chain

Food traceability is critical to the successful determination of a food safety issue and enforcement of a recall. But the massive amounts of data cannot be effectively managed with pen and paper or spreadsheets.

Food manufacturers that do not have proper traceability and quality visibility into their production systems and suppliers are at risk. Further, a recall is more costly if a company does not have real-time tracking that can identify and locate affected lots. Fortunately, technologies exist that allow food and food materials to be tracked and traced from supplier all the way through to finished product. Such technologies create better record keeping, which allows the FDA and food manufacturers to better visualize supply chains during a foodborne illness outbreak and to more quickly determine the source of the problem before a product reaches the store shelf.

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About InfinityQS International, Inc.

InfinityQS International, Inc.® is the global authority on enterprise quality. The company's Manufacturing Intelligence solution delivers unparalleled visibility across the enterprise, from the shop floor to the boardroom, enabling manufacturers to re-imagine quality and transform it from a problem into a competitive advantage. Powered by centralized analytics, InfinityQS solutions provide operational insight to enable global manufacturers to improve product quality, decrease costs and risk, maintain or improve compliance, and make strategic, data-driven business decisions.

Headquartered near Washington, D.C., with offices in Seattle, London, Beijing, and Shanghai, InfinityQS was founded in 1989 and now services more than 40,000 active licenses with more than 2,500 of the world's leading manufacturers, including Kraft Foods, Ball Corporation, Boston Scientific, Graham Packaging, and Medtronic. For more information, visit infinityqs.com.

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