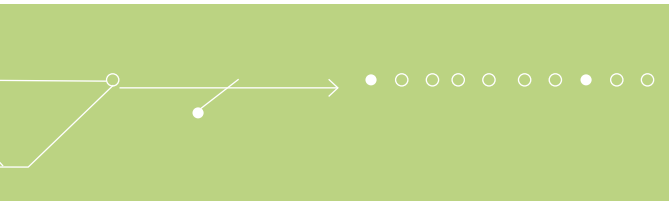
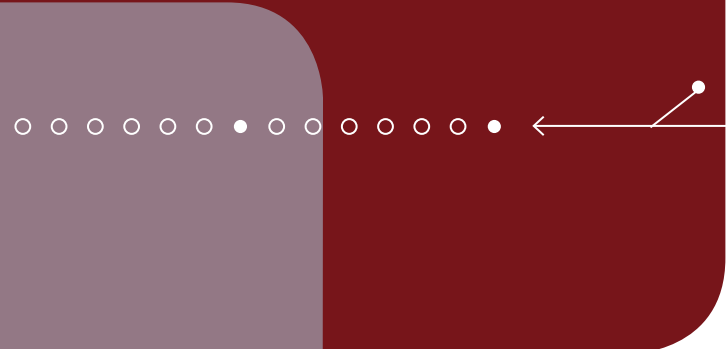


Whitepaper



# 3 Critical Elements

of Supply Chain  
Visibility for the   
Food Safety  
Modernization Act  
(FSMA)



## 3 Critical Elements of Supply Chain Visibility for the FDA Food Safety Modernization Act (FSMA)

### Introduction

The safety and traceability of our food supply has never been more important—and more regulated—than it is today. An increase in concern about contamination, allergies/allergens, terrorist threats and food-borne illnesses makes precise management of ingredients and product whereabouts essential. Driven largely by several outbreaks of contaminated food, the U.S. Food and Drug Administration (FDA) has increased regulations for food and beverage production and distribution. While these changes have emerged to protect consumers and prevent scares – both real and hypothetical – the manufacturers and retailers of these products must now impose a variety of costly changes in their supply chain operations.

In particular, the recent Food Safety Modernization Act (FSMA) (see sidebar) focuses on four major components to improve food safety: prevention, inspection and compliance, response and imports. At its core, the act now provides the FDA with more power to police food companies.

Many companies have begun to re-evaluate and re-engineer their processes to meet current requirements and be more prepared to incorporate the next wave of regulations, whatever those might entail. In addition to governmental regulations, suggested Good Manufacturing Practice (GMP) procedures and Hazard Analysis Critical Control Point (HACCP) plans have been developed to help businesses reevaluate their operations. Effective supply chain execution software applications are critical to tracking product recipes, locations, temperatures, expiration dates and general safety at every point, from the origin of each ingredient to final consumption. Implementing automated, best practices-based systems and processes helps you meet today's stringent compliance initiatives. These supply chain initiatives will also reduce the likelihood of disaster by enforcing strict product-handling rules at every step in the process.

### Snapshot: Food Safety Modernization Act

In January 2011, President Obama signed into law the Food Safety Modernization Act (FSMA). The act represents the first major food safety legislation in 70 years, and grants the FDA with more power to police food companies. At a high level, the act focuses on four major components to improve food safety:

#### 1. Prevention

- Mandatory preventative controls
- Mandatory produce safety standards
- Authority to prevent international

contamination

#### 2. Inspection & Compliance

- Mandated inspection frequency
- Records access
- Testing by accredited laboratories

#### 3. Response

- Mandatory recall
- Expanded administrative detention
- Suspension of registration
- Enhanced product tracking abilities
- Additional recordkeeping for high risk foods

#### 4. Imports

- Importer accountability
- Third party certification
- Certification for high risk foods
- Voluntary qualified importer program
- Authority to deny entry

In addition to mandating increased controls and plans for your own materials and processes, the FSMA also makes you responsible for your suppliers' materials and processes.

## 3 Critical Elements of Supply Chain Visibility for the FDA Food Safety Modernization Act (FSMA)



### What You Will Learn in This Report

In this report you'll discover how the three elements of product traceability – visibility, quality/inspection and recall management – are key to food safety and FSMA compliance at each stage of the supply chain. For each area we will explore the elements as they apply to supplier collaboration, manufacturing, warehousing/distribution and shipping/delivery.

#### 3 Critical Elements of Supply Chain Visibility for the FDA Food Safety Modernization Act (FSMA)

##### Supplier Collaboration

Did you know that with the new FSMA legislation, the compliance of your domestic and international suppliers is now your responsibility? In effect, it's now your job to make sure they are doing their job too. In order to assure products are not adulterated or misbranded, now you must know who each and every one of your suppliers are, and you are responsible for ensuring they too have plans for assuring adherence to food safety requirements. The FSMA requires importers to perform risk-based supplier verification for each international supplier as well.

## 1 Real-Time Visibility

##### Supplier Collaboration

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Of course, you'll need to know if milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts or soybeans are present in the products your company sells, according to the Food Allergen Labeling and Consumer Protection Act. Visibility into the ingredients or raw goods you order for your final products is the first step toward compliance and overall supply chain safety. Not knowing that a potential allergen or contaminate has entered your supply chain may have a ripple effect that could end in disaster if not identified early. A single incident could damage your company's reputation and brand.

Product traceability is essential, and this begins with your supplier network. Visibility into all food and beverage ingredients,

formulations, countries of origin and any changes made to recipes need to be available to you. Supplier enablement systems help ensure a clear communication channel is forged between your supplier network and your manufacturing and distribution operations to make pertinent information available. Some supplier enablement systems offer the option of sharing information using Web portals or system-to-system integration to accommodate a variety of technology resources. These solutions help enforce change management programs by introducing automated information gathering at key points in the process. Likewise, visibility tools can give you direct access to ingredient shipments you will receive from suppliers, and enforce rule-based substitutions where appropriate. Thus, the information tracking on product components begins even before they are received in your warehouse or manufacturing facility.

##### Manufacturing

Now that you have created visibility into the raw and component materials entering your supply chain through your supplier network, it's time to take a close look at what's occurring in your manufacturing operations. Depending on your particular business model, the manufacture of your products could be carried out by your supplier network with finished goods entering your facility for packaging, labeling and distribution. On the other end of the spectrum, you may solely receive raw materials and complete all aspects of manufacturing and packing within your facility. Either way, visibility into the manufacturing process and ingredients used is essential to maintaining product traceability.

A manufacturing execution system (MES) helps you set the stage for continued information flow. Some of the systems available ignore the inventory and material tracking component of manufacturing. Yet, this is absolutely essential not only for lean manufacturing, but also to achieve thorough tracking and traceability. In a nutshell, you'll need to have visibility into what's happening in your manufacturing operations now, and what has happened in the past. You'll need to track what products are made, by whom and on which machines, as well as what ingredients went into each batch and the associated genealogy.

An MES offers visibility into the ingredients being used in production and can establish rules-based alerts to notify managers if a sensitive ingredient has been introduced erroneously. Likewise, visibility to industry standard Overall Equipment Effectiveness (OEE) metrics helps ensure effective use of manufacturing assets. The MES' traceability features also follow the usage of allergens to make sure the proper labels are placed on final products before they are sent into storage or distributed. They may also stamp 'born-on' dates to indicate when the product was manufactured if needed.

### 3 Critical Elements of Supply Chain Visibility for the FDA Food Safety Modernization Act (FSMA)

#### Warehousing and Distribution

Like manufacturing, the warehousing and distribution aspects of the supply chain represent different things to different businesses. Some facilities receive product directly from their own manufacturing operations, while others receive product from outside manufacturing plants. Regardless of the model your business uses, product visibility and history must continue into this phase of your operations.



A warehouse management system (WMS) can date-stamp and assign unique lot numbers to inbound and outbound products or continue to track existing numbers automatically (using radio frequency or RFID) as they enter and exit the facility. Date stamps and born-on manufacturing indicators are product attributes maintained in the system, enabling operators to draw on pallets in the correct order. This is important not only for traceability records, but also to have visibility into expiration dates that support FIFO- and LIFO-based picking and rotation.

Other inventory management functions use this tracking information. During the put-away phase, stock location and rotation should be based on established, system-directed rules that avoid mixing products in locations that could affect integrity. For example, a product that has been rinsed should not be put away in a manner that would allow this excess water to drip onto another product or packaging material.

Traceability must also be preserved during value-added service management such as packaging and product bundling. In these situations, individual products are pulled from master lots to become part of a new group. For example, this could mean bundling a fruit, beverage and sandwich into a lunch kit. The master lot number for each individual item should be recorded to maintain traceability as the new grouping moves through to the consumer. Product bundling is a common practice for retailers, especially club stores. One retailer might want a three-pack simply because its competitor sells a two-pack. These requests are most efficiently executed in distribution to support a postponement strategy. Another common occurrence is that canned products will be stored as “bright stock,” meaning they are just cans without labels. Then as demand is established, the cans are run through a labeling operation to give them a name brand or store brand label, depending on the order.

Another noteworthy capability is event management, which can be used throughout many phases of the supply chain, but is particularly helpful in warehousing and distribution. Pre-configured alerts can notify managers about upcoming expiration dates, key shipment arrivals, and late shipments to maintain product freshness. The system can also notify you of cross-docking opportunities to load received products directly on an outbound carrier.

#### Shipping and Delivery

Real-time visibility into your product during the warehousing and transportation stages is important to make sure expired, damaged or recalled product is not shipped to customers. The hand-off to transportation represents a critical point of information transfer in the food and beverage supply chain. The warehouse management and transportation management systems (TMS) must communicate the detailed tracking information to continue the traceability path. Transportation providers must retain records on their shipments and destinations, and the systems governing in-transit products must continue to track expiration dates.

Even before products leave the dock, the TMS in place ensures the appropriate carrier and mode are used for transport. This information is often communicated by the WMS and includes notifications regarding whether a refrigerated truck or dry van will be needed. During transport, visibility into which shipments are on the vehicle will help ensure expiration dates are within the acceptable window. Once products arrive at their destination, delivery confirmations should be entered that confirm execution of the transportation phase. This data should flow from carriers back to shippers to close the information loop and maintain traceability from source to consumption.

## 3 Critical Elements of Supply Chain Visibility for the FDA Food Safety Modernization Act (FSMA)

### 2 Rigorous Quality and Inspection

#### Supplier Collaboration

Not only do you need visibility into the actual ingredients you receive from suppliers, but you'll also need validation from an outside authority that the suppliers' facility, equipment and overall processes meet regulations for quality and safety. Furthermore, when effective (two years from signing), the FSMA requires you and your suppliers to do your testing in an accredited lab, with results being sent directly from the lab to FDA. The legislation also increases inspection frequency of high-risk facilities.



Your supplier enablement system can be set up to request the latest inspection records and note any intolerances which may affect the products you receive. You'll also want to push enforcement of ingredient quality to your suppliers to avoid variability in what they ship.

RFID and sensor data can be valuable tools for product monitoring at this stage of the supply chain, especially for items requiring temperature control. An RFID tag can be set to send an alert if the temperature goes out of a predetermined range and exactly where the shipment was when this occurred. Having this data in your supply chain management system could pinpoint a supplier that is not well-equipped to manage the quality controls you need for product freshness and safety.

Over time, you'll be able to access reports on which suppliers

perform well and which did not meet your expectations, helping you renegotiate contracts and establish better pricing with data to back up your decisions, and also facilitates the rigorous documentation you must produce immediately upon FDA request.

#### Manufacturing

Quality management and manufacturing go hand in hand. There are many regulatory guidelines that govern how manufacturing processes must be carried out. The FSMA mandates controls be put in place to reduce or prevent food safety hazards reasonably likely to occur in your operation, with reanalysis required at least every three years.

An MES sets the stage for thorough, enforceable rules surrounding a host of quality and inspection processes. These include process control, specification management, work dispatching, sampling and operator certification, as well as machine status and use.

The MES uses processing controls to help reduce the instance of cross-contamination for machines that produce a variety of products, especially when some of those contain ingredients with special handling requirements. Cleaning and changeover rules can become routine, reducing or eliminating the occurrence of allergens where required. Sampling management enforces when samples need to be taken and exactly what data should be captured and tracked. This supports traceability by showing a history of which tests were performed when, and on which products and batches.

#### Warehousing and Distribution

Simply put, quality assurance and accurate inventory control help eliminate recalls. WMS software can direct and optimize work activity quickly to put products in the right storage locations. Ensuring that goods are stocked in freezer and refrigerated zones means their quality and freshness will be preserved. Sensor and RFID technology can be helpful to regulate environmental storage in such areas and send notifications if temperatures move out of acceptable ranges.

Likewise, picking products based on FIFO and LIFO rules help manage expiration dates and ensure stock is rotated properly. The WMS will track this information and direct workers to perform put-away and picking tasks accordingly, and all activities are recorded in the system.

Not only is traceability important to maintaining quality in the warehouse and distribution phase, but security is also a factor. The WMS can help you leverage technology that provides tampering control, making it difficult for people to carry out dangerous activities.

## 3 Critical Elements of Supply Chain Visibility for the FDA Food Safety Modernization Act (FSMA)

### Shipping and Delivery

Maintaining product quality and freshness during transit requires robust systems and real-time information transfer. The WMS will communicate with the TMS any vehicle requirements (refrigerated or dry vans), which will be verified upon departure. RFID can also be used to monitor temperature levels to make sure refrigeration and heat don't become an issue. Likewise, automatic expiration date tracking capabilities extend from the WMS to the TMS to alert you of product that could expire during the transportation phase. These systems will leverage visibility to expiration dates and order destinations to plan shipments in a way that maximizes available stock. For example, goods produced on the West Coast have a longer shipment window for fulfilling orders with nearby shipping destinations than for orders shipped across the country.

A TMS or best-of-breed yard management system (YMS) can track fuel remaining in a trailer's refrigeration source to help ensure the shipment can safely remain in the yard (or on the road) without having an entire trailer of product spoiling before it reaches its destination. You can use your system to track seals used on trailers. Broken seals at the destination can provide a clear indication of tampering.

## 3 Fast, Reliable Recall Management

The FSMA gives the FDA the power to mandate recalls and suspend your FDA registration if the FDA finds a possibility of adverse health risk in your operation. If your business is ever faced with this situation, your ability to perform fast, thorough recalls could save both your brand name and your customers from serious consequences.

### Supplier Collaboration

Recalls can become necessary at any point in the supply chain. Performing due diligence by tracking all ingredients and formulations is a strong preventative measure, but having a supplier enablement system or similar application in place to locate ingredients later in the supply chain is also important – and necessary. The FSMA requires that all ingredients be traceable throughout the supply chain, placing a need for recall management practices squarely on the shoulders of many food and beverage suppliers. This legislation calls for advanced product tracing abilities and additional record keeping for high risk foods. Although many companies are capable of meeting these requirements on their own today, it becomes more complicated when there are various trading partners involved.

### Manufacturing

Many companies still rely on inefficient, paper-based processes that increase the cost of product recalls, not to mention make fast action impossible. By contrast, manufacturing execution systems pull data from the automation layer or transactions from shop-floor employees to tie lot numbers or other data back to the appropriate work order or demand signal. Your ability to access transaction and genealogy history through Web-based reports will also help you view unit histories and trace products accurately on both the supplier and warehouse sides of the business.



### Warehousing and Distribution

A recall is the ultimate test of your systems' ability to transfer and maintain accurate data throughout supply chain operations. You will need to notify customers within hours of the recall that some of their shipments may be affected and should be either destroyed or returned. Rapid retrieval of traceability records and customer notification are key to helping you meet federal guidelines and prevent any harm. Your ability to narrow down the scope of the recall will be critical to identify exactly which products are at issue and which are not affected.

The WMS will need to identify lots that left the warehouse and arrived at their destination. The final ship-to address showing what was received and by whom should be readily available if you have a WMS and TMS system in direct communication. RFID can be useful to track shipments in both mock and real recalls to ensure fast action.

### Shipping and Delivery

Your TMS will give visibility to what left your warehouse and where it is en route. This can be valuable information if you are able to pinpoint products still in transit and can stop the truck before it even reaches the customer. Accurate records of what has been shipped and the final delivery destination will help you accomplish the final step in traceability and complete a recall quickly.

## 3 Critical Elements of Supply Chain Visibility for the FDA Food Safety Modernization Act (FSMA)

### Selecting a Supply Chain Management Software Provider With All the Attributes You Need

In order to protect and grow your business and reduce risk, you need to select a supply chain software vendor with all the key functionality the food and beverage industry requires – as well as room for growth and evolution of your business. But how do you make sure you choose the right one?

- Look for a full suite of solutions. Look for a vendor committed to keeping their entire line of products in-step with food and beverage industry and customer requirements. This reduces the necessity of integrating disparate supply chain applications and simplifies the adoption of additional applications and features as you grow. Plus, you'll never need to worry about a technology barrier to food safety.
- Research the industry track record. Does the vendor really know your industry? Have they developed features and functions to help you comply with food and beverage industry requirements? Do they have a happy and referenceable customer base?
- Is the system affordable...over the long run? Many packages

may seem like a great value until you estimate the cost of making changes to fit the software to your business processes, and to upgrade the systems regularly. Ask the vendor about how changes can be made and the real cost of upgrades.

- Check on supplier relationships. If the vendor is truly committed to your industry, they will demonstrate this in their relationship with food and beverage industry suppliers. Check to see if the vendor has supplier relationships and/or certifications.
- Forecast operational growth and change. Your next supply chain software provider can be the last one you need, if you ensure the suite can handle current and future needs.
- Consider the integration factor. Make sure the supply chain provider you choose can integrate easily with your existing business systems, such as your ERP.
- Know the provider as well as the software. Don't make the mistake of focusing only on the software and not on the value of the partnership with the vendor. Make sure you understand each vendor's implementation methodology and how new software versions are developed and released. Check to see if the vendor has a user group and an annual user conference.