



## EXECUTIVE BRIEF

# How CloudSuite Food & Beverage facilitates FSMA compliance

The FDA Food Safety Modernization Act (FSMA) requires that food and beverage companies take a more proactive approach to food safety. This is a shift from the more reactive approach that food and beverage companies have historically followed. With FSMA in place, companies must identify risks, create procedures for mitigating hazards, and execute against those procedures to ensure all threats to the safety of the food supply chain are contained, as well as demonstrate that their programs are valid and that they are continually being improved upon. As ambitious as this may seem, what many don't realize is that the software systems they already use, such as Infor CloudSuite™ Food & Beverage, can already handle this shift and provide a solid foundation to complete their FSMA compliance plan.

This paper details some of the more exacting aspects of FSMA and discusses how CloudSuite Food & Beverage can help food and beverage companies address these challenges.

## Why FSMA compliance matters

Each year, 48 million people in the US get sick from a foodborne illness, while 128,000 are hospitalized and 3,000 die, according to the Centers for Disease Control.<sup>1</sup> In response, the US Food and Drug Administration's (FDA) [Food Safety Modernization Act \(FSMA\)](#) seeks to ensure food safety and compliance—and reduce outbreaks of illness.

**Infor CloudSuite Food & Beverage provides the right tools and infrastructure to identify and react to compliance challenges, while complying with FSMA mandates.**

While the initial set of rules for FSMA were implemented in 2015, new rules will continue to be phased in through 2024.<sup>2</sup> These rules require food and beverage companies to be more proactive in preventing food safety problems. Not only does that mean establishing preventive controls, but also validating and verifying them—while also documenting every step along the way. Food and beverage companies, which have historically been more reactive to events such as recalls, must now commit to a drastic change in how they do business to keep up with regulatory requirements.

Track and trace tools have long been part of the food and beverage industry's preparedness planning in the event of a recall. Just one recall can have sweeping, negative effects on a business. But with FSMA, food and beverage companies must take a broader view of the safety and quality concerns that can affect their products and their business—and documentation is a crucial part of FSMA.

FSMA also requires tighter record and documentation storage. This means having the document management tools and processes in place to ensure traceability, reliability, and compliance throughout the entire supply chain—to prevent contaminations and non-conformance.

FSMA compliance stresses that the safety of consumers is paramount. By adhering to FSMA's quality management mandates, and taking the right steps today, food and beverage manufacturers, central kitchens, distribution centers, food importers, and even transportation companies can ensure full documentation and traceability throughout their supply chain—as well as high-quality products.

## What is FSMA's main challenge for F&B companies?

When it comes to FSMA compliance, the need to increase and improve documentation and record storage cannot be understated. The amount of documentation that food and beverage companies will need is going to continue to grow. Infor CloudSuite Food & Beverage can help maintain the physically signed documents that may be required.

FSMA requires written, documented compliance from food and beverage companies that includes:

- **Hazard analysis**—Documentation to identify and evaluate known and foreseeable hazards for each food type stored, packed, processed, or manufactured at a specific facility. This includes human food and animal feed, as well as raw foods such as produce.
- **Preventive controls**—To maintain compliance with hazard analysis needs, companies must create a food safety plan that includes preventive steps, monitoring procedures, corrective actions, good hygiene and sanitation practices, and labeling requirements.
- **Foreign supplier verification program**—According to the FDA's final rule on the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals, importers must "perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards."<sup>3</sup>
- **Corrective action procedures**—These are written procedures that should be taken if a facility is not in compliance, which means documenting problems with the controls and food safety—and re-evaluating the plan.
- **Sanitary transportation**—From plants to trucks to receiving facilities, companies must document all safety procedures and training for the safe and sanitary transportation of food.
- **Recall plan**—This written plan includes all of the steps that are necessary to document and take action in the event of a recall. The plan also includes documentation for notifying all relevant parties to remove and dispose of products that have been contaminated.

Compliance with FSMA will require food companies to think differently about their processes and the data they're collecting. They will need to use the data already being gathered across all aspects of their operations; this is more than just manufacturing data (e.g., tracking visitors, employee training records, and vetting suppliers). New data elements pertaining to suppliers, raw materials, environmental elements (transport conditions, temperatures, metal detectors, etc.), and the products they produce may need to be collected, analyzed, and finally addressed if a non-compliance surfaces.

Most business processes produce data and the vast majority of that data shows that all conditions are “in-compliance.” However, most companies that deal with food have many processes across their organization. How can these processes and systems be enhanced to identify and react to these threats to improve a company’s quality and compliance?

Fortunately, Infor CloudSuite Food & Beverage provides the right tools and infrastructure to identify and react to these threats, while complying with FSMA mandates.

## How Infor CloudSuite Food & Beverage can help

Infor CloudSuite Food & Beverage is a purpose-built, industry-specific solution suite available in the cloud, on-premises, or as a hybrid solution that is easy to upgrade and fully secure. The suite uses our social collaboration engine, Infor Ming.le®, which facilitates internal and external communications between customers and their suppliers to help speed the documentation of all of the supply chain processes for producing high-quality food and beverage products.

### Document management

Infor CloudSuite Food & Beverage's document management tools give companies in-context access to a centralized document repository accessible within the solution, so users don't have to open a separate application. This document management system reduces the need for paper-based systems and delivers real-time information to decision-makers. The latest version is compatible with Infor ION®, which enables real-time alerts to additional Infor or third-party applications when document changes are made.

Infor CloudSuite Food & Beverage's document management tools are also equipped with both optical character recognition (OCR) and intelligent character recognition (ICR) capabilities for more complete document capture. This allows machine-printed and hand-printed text to be converted into digital formats, to diversify the types of information that can be used through the application, in real-time.

## Create detailed documentation from inception to delivery and all along the supply chain with CloudSuite Food & Beverage

### Specification management

When it comes to specification management, understanding the difference between “food safety” and “product quality” is key. A product can meet all its quality standards and still not be safe to eat. Conversely, a product may be safe to eat and not meet its quality standards. The communication of specifications to suppliers and the shop floor is the cornerstone of any quality and food safety program.

Infor PLM for Process, a process manufacturing product lifecycle management (PLM) solution, can ensure that product specifications are both comprehensive and that regulatory compliance needs are met. Infor PLM for Process meets FDA 21 CFR Part 11 and can be added to Infor CloudSuite Food & Beverage as a standalone solution.

At the same time, production scheduling can be dynamic and fast paced. If a line goes down, schedulers need to quickly find another way to get product out the door. Among other benefits, Infor PLM for Process can provide the detailed specifications to alert schedulers that an allergen may be present and the production of that product on that line may require additional steps, such as sanitation or changes in temperature.

### Labeling management

Documenting all recipes and labeling data can help food and beverage companies proactively prepare for FSMA compliance. For many companies that want to document the development of their new products or modify existing products and formulas, Infor PLM for Process can serve as the foundation for documenting all of their recipes and labeling data.

In addition, because Infor PLM for Process provides real-time data about ingredients and formulations, this solution can help improve and automate the labeling process. Infor PLM for Process provides a single source of information that includes data from inside and outside the enterprise, presented in-context to the user.

The automated labeling content feature in Infor PLM for Process allows food and beverage manufacturers to generate all the required data on all their product labels. In this way, food and beverage manufacturers can be assured that they not only know where all of their ingredients and products are sourced from—but they can also document this information to meet specific regulatory needs and maintain FSMA compliance.

Infor PLM for Process—whether added onto Infor CloudSuite Food & Beverage or as a standalone solution—provides one central repository where all of the relevant information about a company's products is available at the click of a button.

### **Quality control and laboratory inspection**

Quality is a top concern for food and beverage companies. Just one recall can have a significant impact on a company's future. With FSMA shifting the quality management and compliance focus from a reactive to a proactive approach, having the right quality control is critical.

Infor CloudSuite Food & Beverage contains a fully integrated quality and lab inspection module that ensures production control procedures as well as product-lot inspections are pro-actively executed along the supply chain. With Infor CloudSuite Food & Beverage, specifications and test procedures can be specifically designed down to individual processes and products to force appropriate test levels according to the risk-profiles related to different suppliers, manufacturing processes and products.

By using integrated and pro-active testing procedures companies can minimize the risk of shipping non-compliant products. Additional test-procedures and actions can be triggered to investigate the cause of the product issues in the instance that a non-compliant product has been returned.

### **Traceability**

Traceability ensures that manufacturers can meet high standards for food quality. For FSMA, this also means staying in compliance with the supplier verification program. Companies can use the Graphical Lot Tracker within Infor CloudSuite Food & Beverage to create a repository of track-and trace-data.

The Graphical Lot Tracker can be used as part of a manufacturer's everyday activities to create a database for product tracking. This information can be used all along the supply chain—from sourcing and procurement to delivery and replenishment on retailer shelves.

Then, all products and ingredients—from cuts of meat, to food dyes, fresh produce, and other food types—can be accurately traced back to their source, along with each step they have made through the supply chain.

In addition to FSMA compliance, tracking and analyzing this data can be especially beneficial in the event of a quality issue or recall. In such cases, the Graphical Lot Tracker can be used to take corrective actions—all of the transactions entered into the system are automatically validated to identify any gaps or inconsistencies and ensure quality. The solution can also isolate the point at which a contaminated product or ingredient entered the supply chain.

A rapidly growing number of Infor customers have successfully implemented the Graphical Lot Tracker to trace all aspects of their products, down to the ingredient level and through the supply chain. In fact, Infor was one of the first companies to develop an advanced lot traceability solution with advanced data mining capabilities that are accessible in an intuitive graphical presentation.

### **Recall preparedness**

Even the best, automated traceability systems can't eliminate problems caused by food contamination, disease outbreaks, or even accidental mishandling of food products. Accurate and transparent traceability tools, however, effectively reduce risk exposure by allowing food and beverage manufacturers to identify, isolate, and correct problems quickly and efficiently. Using these tools to act quickly not only protects public health, but it also helps to reassure consumers and minimize the financial impact of such an event.

FSMA documentation requirements understand this. That is why part of having a proactive recall management process involves re-evaluating all of these documented processes after a recall—and learning how to avoid the risk of another.

Many recalls are the result of labeling inaccuracies. There are two key areas where label compliance can be an issue here. The first is ensuring that the listed ingredients match what is actually in the product, with regards to completeness and correct order. Failure to disclose all ingredients, especially if there is potential for allergic reactions, can result in a recall. The second is ensuring a product label's nutritional and health claims are accurate and will comply with all government standards.

Due to changes in formulas, as well as raw material fluctuations, food and beverage manufacturers often find it challenging to produce labels that provide accurate product information. Infor PLM for Process is designed specifically to address this challenge, especially for FSMA compliance.

### Asset management

Properly managing plant assets to decrease downtime and control expenses makes asset management a core requirement of any FSMA compliance plan. Food and beverage companies must ensure that their equipment assets (tanks, pumps, ovens, and filling lines) are being properly maintained to prevent contamination and meet quality mandates.

Infor EAM, our enterprise asset management application, meets 21 CFR 11 requirements, and provides tools for preventive maintenance, inspection, and calibration. Infor EAM can help companies maintain compliance and prevent food safety risks by helping them identify and track the proper maintenance and cleaning procedures for their production equipment.

Moreover, to reduce the risk of ingredient contamination and meet quality and compliance mandates, including label production, Infor CloudSuite Food & Beverage has alerting and rapid escalation technologies for early and quick detection of problems with assets. Infor CloudSuite Food & Beverage can help track all of a company's asset management needs to catch non-conformances and quality issues before they become a greater problem.

### Training and hiring

Not only will companies be required to complete additional training to stay current with FSMA requirements, but at some of their facilities they will need to develop new certification programs for documentation and data collection. FSMA will require documentation of all of these training requirements—and that goes for the entire supply chain, from manufacturing centers to the sanitary transportation of products.

These training programs will also need to be audited regularly to make sure they are compliant with FSMA. In addition, training and hiring qualified inspectors and workers is a complex undertaking. Infor CloudSuite Food & Beverage provides a central repository of relevant compliance laws and regulations—including human capital management (HCM) tools that help manage employee certifications, training, and talent so the right people are in the right positions.

### How you benefit

Infor CloudSuite Food & Beverage has all of the tools food and beverage companies need to create detailed documentation to maintain FSMA compliance—from inception to delivery and all along the supply chain. These tools can help companies to proactively prepare their businesses to comply with FSMA and ensure that they are producing high-quality products.

<sup>1</sup> "Key Facts About Food Poisoning." Centers for Disease Control and Prevention, March, 2020.

<sup>2</sup> "FSMA Final Rules: Key Dates," U.S. Food & Drug Administration.

<sup>3</sup> US Food & Drug Administration, "FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals," Aug 18, 2020.

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