

How to Automate a FSMA-Ready Food Safety Plan

And how technology helps you automate, streamline and improve FSQA whether you'll be impacted by FSMA or not!



Position Paper

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Introduction



As part of FDA's Food Safety Modernization Act (FSMA), food and beverage companies that must comply with FSMA have to create and implement a Food Safety Plan that is far more complex than many plans in place today. And many experts agree that in order to fulfill the requirements of these plans, automation will be mission critical.

Not only can technology help keep track of – and ensure completion of – Prerequisite Programs (PRPs), Corrective/Preventive Actions (CAPA), FSMA's in-depth documentation requirements and more – the right technology can also help create bottom-line Return on Investment (ROI) by automating, streamlining and improving overall food safety and quality assurance (FSQA) operations.

Food Safety Chain Management technology is being touted as the most effective prevention-focused software technology to help manage FSMA Food Safety Plans while helping companies stay within their Key Performance Indicators (KPIs) and lower cost of goods made.

This position paper will cover:

- How Food Safety Chain Management technology works
- The six key components of a FSMA Food Safety Plan
- How Food Safety Chain Management automates each of the six key components with associated ROI

What is Food Safety Chain Management Technology and How Does it Work?

Food Safety Chain Management is a technology innovation designed to help prevent food safety and quality incidents before they happen or get “out of control.” With realtime data collection and analysis to specifications – along with automatic alerts when deviations are detected – Food Safety Chain Management helps prevent non-compliant ingredients and raw materials from coming in, and non-conforming finished products from going out. Additionally, Food Safety Chain Management helps ensure FSQA workflow, processes and documentation – while also creating a central repository of FSQA data for trending, assessments, reporting and audit readiness.

Let’s review the Diagram A below for a high level look at how Food Safety Chain Management technology works.

1. All regulatory requirements, for FDA and USDA programs – along with requirements for non-regulatory safety plans, such as GFSI schemes – are defined within the Food Safety Chain Management system.
2. All company specific procedures and requirements are also set up within the system. Examples include PRPs for Preventive Controls, CCPs for HACCP plans, quality attributes for customer specifications, audit forms, supplier documents for approved vendor programs, maintenance schedules and more.

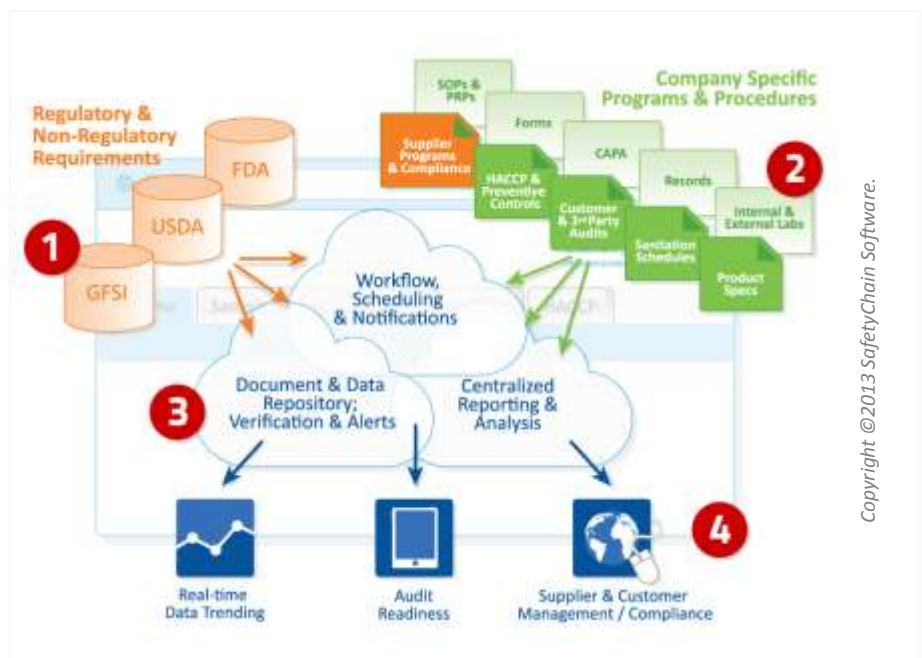


Diagram A – How Food Safety Chain Management Works

3. All processes, procedures and documents set up in the Food Safety Chain Management system have assigned due dates or routine schedule times for completion. The system automates all associated workflow, with automatic notifications issued when documents or processes are due – calibrating metal detectors prior to a manufacturing line start-up, ensuring supplier inbound COAs are received, or taking temperature test assessment samples prior to harvesting a produce field, for example. Auto-notifications help ensure compliance and help avoid expensive rework.

Additionally, all safety and quality data/test results – from supplier COAs, internal or 3rd party labs, processing equipment (such as weight or cooling equipment) and more – is analyzed in realtime for verification against specifications. When everything is within spec, outbound COAs are generated. When non-conformance is detected automated alerts are sent to the appropriate key stakeholders so CAPAs can take place in the fastest manner possible and keep the value chain moving.

All FSQA data and results, documents, CAPAs and more are stored in a central repository of data – regardless of the number of product groups and/or facilities – with unalterable time/date stamps.

4. The central repository of data provides for in-depth risk assessments, performance trending, continuous improvement, monitoring of KPIs, audit preparation and much more.

The end result? Realtime data trending to be able to fine-tune and make adjustments to specifications, processes and procedures ... the ability to respond on-demand to regulatory, 3rd party and customer inquiries and audits ... and comprehensive management of supplier programs and customer commitments.

Components of a FSMA Food Safety Plan

Now that we've established a foundation of how Food Safety Chain Management works, the next sections of this paper will examine the six key components of a FSMA Food Safety Plan, as outlined in Diagram B, and how Food Safety Chain Management helps automate these requirements:

1. Product & Facility Plan
2. Risk Assessment
3. Preventive Controls
4. Monitor, Verify, Validate
5. CAPA & Reanalysis
6. Document

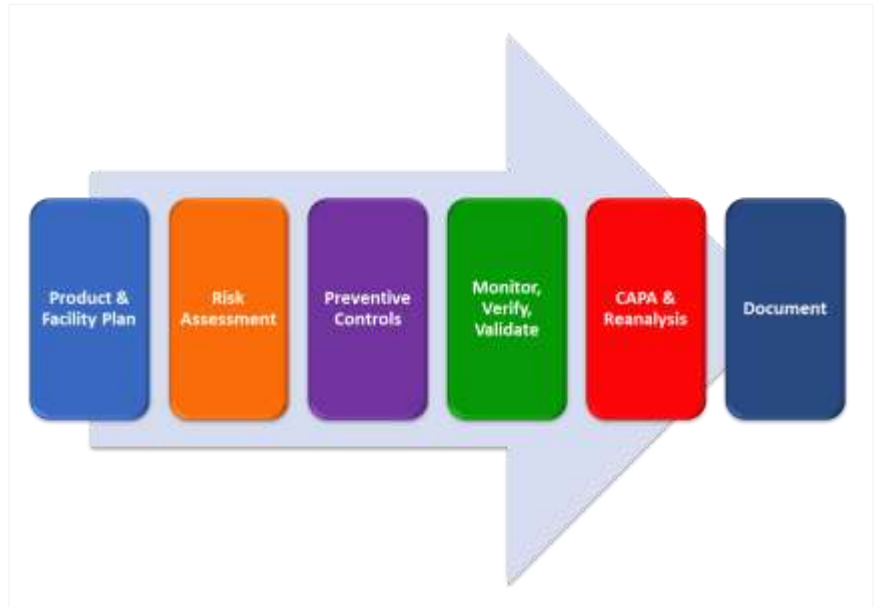


Diagram B – The 6 Components of a FSMA Food Safety Plan

Product and Facility Plan



FSMA requires that impacted food and beverage companies have a *written* food safety plan for every product (or groups of similar products) and facility.

This requirement could mean then literally thousands, if not even tens of thousands depending on the size of your company, of PRPs, CCPs, specifications and more ... not to mention the potentially overwhelming increases in people hours to track and ensure that the plans are being followed.

Food Safety Chain Management helps manage Food Safety Plans – regardless of the number of products and/or facilities companies may have. Capabilities include the ability to:

- Define an unlimited number of specifications, Preventive Controls/PRPs, CCPs, Standard Operating Procedures (SOP), Good Agricultural Practices, supplier requirements (including documents associated with FSMA’s Foreign Supplier Verification Program) and more
 - ✓ All of the definitions can also be electronically identified by product/product groups and facility
- Automatic task scheduling allows you to set times/due dates for all PRPs, SOPs, CCPs, etc.
 - ✓ Initial and escalating alerts can be defined to further facilitate completion
- All of the above are maintained, regardless of the number of facilities and/or locations, in a central repository of data with dashboard access for monitoring, trending, audits and a comprehensive look at your entire operation – not only helping keep food safe but also helping with continuous improvement and finding ways to contain costs

Risk Assessment

For your safety plan to be FSMA compliant, you must assess all risks that are reasonably likely to occur. This has traditionally been a daunting task because the information required for such assessment was typically in many different formats and locations – requiring many, many hours of manual entry for analysis. With Food Safety Chain Management:

- All FSQA test results, inbound COAs, CAPA data and more are accessible from a central repository of complete and accurate data
- This data then lends itself to in-depth analysis and trending in order to assess risks



Preventive Controls



Once risks are assessed, the Food Safety Plan must contain Preventive Controls designed to do all that is possible to prevent the risks that are reasonable likely to occur from occurring. In addition to HACCP CCPs, Preventive Controls also cover plans for things like process controls, allergen controls, sanitation controls, training and recall plans.

Food Safety Chain Management helps you manage Preventive Controls with the ability to:

- Set up all Preventive Controls with defined schedules and notifications
- Have inbound COA information – and/or data from internal FSQA tests – analyzed against specifications in realtime
- Generate realtime alerts when a control isn't completed or FSQA test results deviate from specs

Monitor, Verify and Validate

A FSMA Food Safety Plan calls for continuous monitoring, verification and validation of Preventive Controls – after all the idea is to *prevent* food safety outbreaks vs. respond to them after the fact.

In essence, monitoring, verifying and validating means saying what you're going to do, making sure you're doing it, and making sure that it works. Food Safety Chain Management supports these efforts with the ability to:



- Again, define all PRPs, CCPs, etc., in the system so that you have the components of the plan documented – and ensure they are being completed when due via notifications from automated task scheduling capabilities
- Electronically gather all related data and information for realtime assessment against specifications
 - ✓ Data can include information and test results from suppliers, internal and 3rd party labs, equipment and even during transportation – from, for example, temperature probes that communicate realtime data to the Food Safety Chain Management system
 - ✓ In many cases, data can also be captured remotely on smart mobile devices – pre-harvest assessment information, for example, during pre-harvest inspections
- Validation is achieved via realtime analysis against specifications and Food Safety Plan parameters, as well as realtime alerts on deviations, deficiencies and omissions

CAPA and Reanalysis

FSMA Food Safety Plans require that:

1. When Preventive Controls fail, Corrective and Preventive actions be put in place
2. That plans and controls must be reassessed periodically, to ascertain if there are areas for improvement, and also when there's a food safety incident caused by a failure in Preventive Controls

Food Safety Chain Management helps you comply with these two requirements with:

- Realtime alerts that help ensure that CAPAs can be taken at the earliest point possible when deviations are detected
 - ✓ Time/date stamped CAPA documentation, including, when required or desired, before/after digital photos
- Upstream/downstream/internal visibility for root cause analysis and tracing how/when a safety deviation occurred
- A comprehensive database of all PRPs, CCPs and FSQA data for reassessment and continuous improvement



Document



With FSMA, it is often said that “if it isn’t documented you might as well not have done it.”

Everything must be documented – the programs in the Food Safety Plan, proof of completion and validation, all test results and supplier documents, CAPAs and more. Food Safety Chain Management facilitates comprehensive documentation with:

- A centralized repository of all plan elements, test results, proof of PRP/CCP/SOP/GMP/GAP completion, CAPAs and more – helping you respond to audits and FDA/customer inquiries on demand; all data has unalterable time/date stamps for greater FSQA efficacy
- Additionally, trending and benchmarking on the central repository of data helps you achieve ROI via:
 - ✓ Supplier scorecarding
 - ✓ Adjustments to specifications for greater yield and product performance
 - ✓ Prevention of rework
 - ✓ The ability to help prevent withdrawals, rejections and recalls
- Reduction of errors and costs associated with manual data entry

SafetyChain for Food

SafetyChain Software's SafetyChain for Food is the food & beverage industry's leading Food Safety Chain Management solution.



SafetyChain for Food is a comprehensive FSQA solution that stands alone or complements existing investments. SafetyChain for Food:

- Supports all participants in a food supply chain, including suppliers/growers, manufacturers/co-packers, distributors/brokers/importers and retailers/foodservice
- Is offered in a highly secure cloud platform for a cost-effective solution that makes it easier for all participants in a food chain to work together
- With SafetyChain for Food, you license only the modules you need; pricing is fully transparent with no hidden fees or per-user pricing
- SafetyChain provides a full-service implementation model so that you can be up and running without drain on already overworked FSQA and IT departments

SafetyChain for Food helps you be FSMA-ready with our **FSMA FIVE**:

1. **Collect and assess** data in realtime
2. **Mobile data collection**/assessment at the earliest point possible, even from the field
3. **Automate** PRPs, CCPs, SOPs, Good Agricultural Processes and more
4. **Document** all program parameters, test results and CAPAs
5. **Create a central repository** of unalterable, time/date-stamped safety data

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