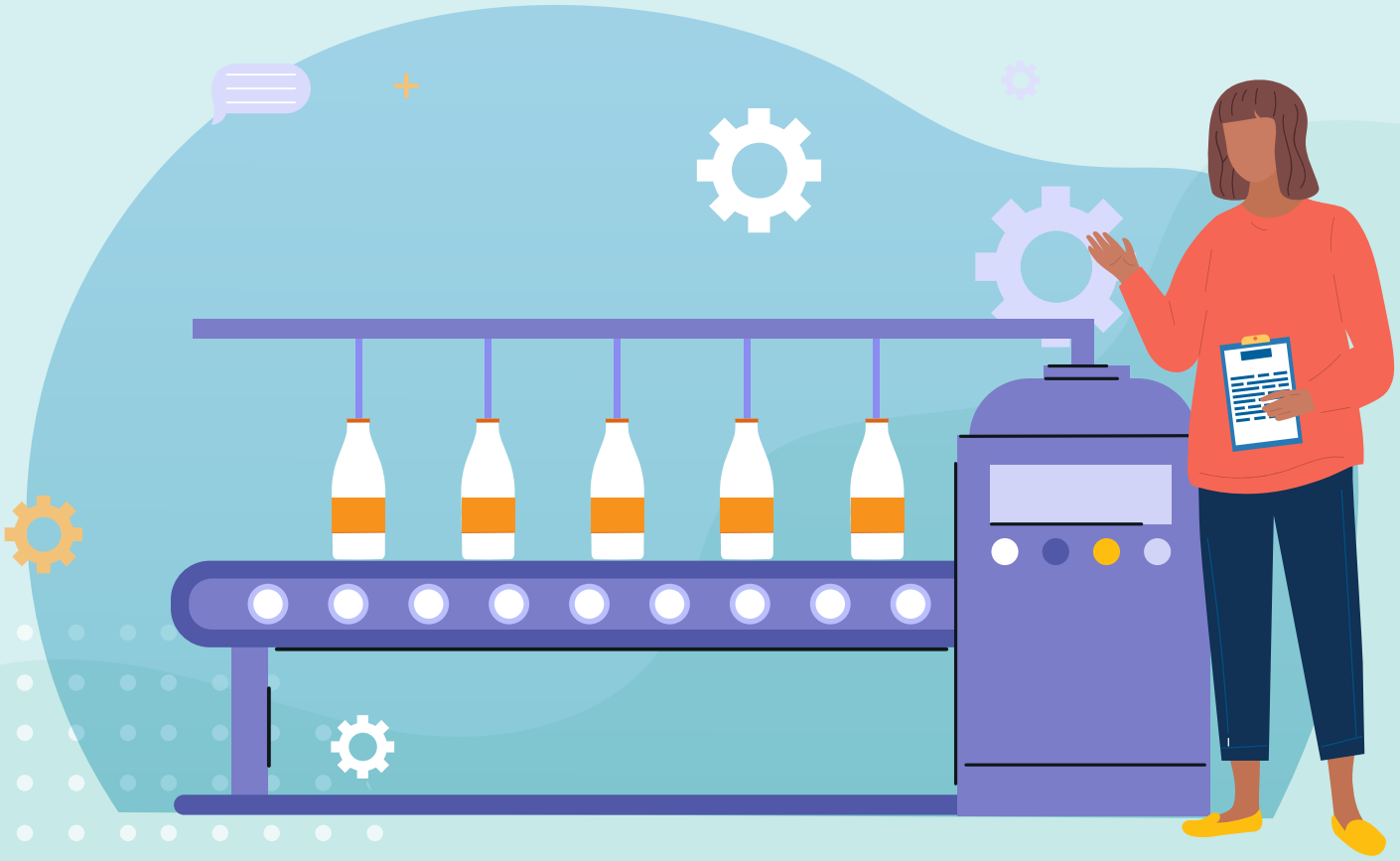
TRACEGAINS

Raise the Bar on Your Food Safety Plan



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Upgrade Your Food Safety Plan

Better technology, changing consumer trends, and advanced processing methods deliver a wealth of opportunities to improve safety and nutrition at food manufacturing plants. As a result, food systems have become even more complex and intertwined, blurring lines of regulatory responsibility.

More recently, the U.S. Food and Drug Administration's New Era of Food Smart Food Safety initiative, which the agency launched at the start of the pandemic, wants companies to embrace digitization and eventually eliminate paperwork. While it's a move most analysts expect to take up to a decade, it's inevitable. Digital records, FDA officials argue, will enhance traceability, improve predictive analytics, allow the agency to respond more rapidly to outbreaks, and foster the development of stronger food safety cultures.

A comprehensive Food Safety Management System (FSMS) is critical to maintaining product quality and protecting consumers for food manufacturers. And the most vital component of any FSMS is the Food Safety Plan (FSP). The FSP is the foundation for ensuring everything coming off the production line is safe.

Who Drafts the FSP?

A preventive controls qualified individual (PCQI) must draft the FSP or at least supervise its development. A PCQI is someone trained to develop and implement food safety systems and can achieve qualification through job experience or FDA-certified training. Regulations don't require the PCQI to be a facility employee. However, the facility owner, operator, or agent in charge must sign off on and date the FSP upon completion or whenever they make changes.

UPGRADE NO. 1

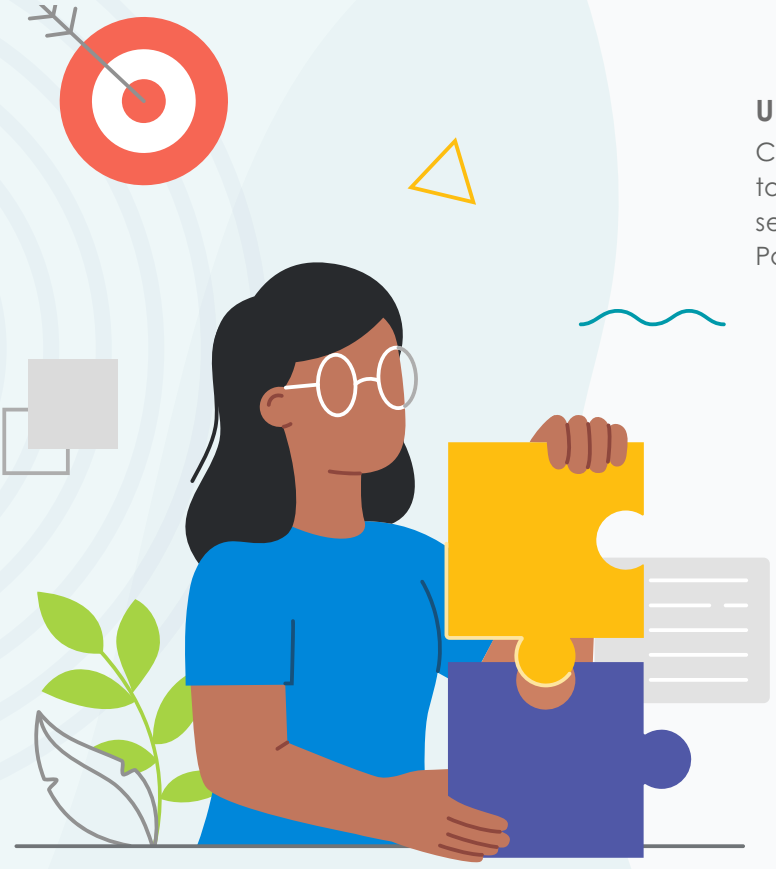
As part of nurturing a greater food safety culture at your plant, consider adopting a backup PCQI. It pays to have multiple people trained in corrective actions, the jargon, and all the ins and outs of the FSP. This also helps encourage buy-in across the organization.

Basics of a Food Safety Plan

According to the FDA, an FSP consists of "the primary documents in a preventive controls food safety system that provide a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury."

The FSP also must contain a compilation of written documents that spells out the activities that ensure food safety during manufacturing, processing, packing, and holding. Those written documents include:

- A hazard analysis to identify whether hazards mandate preventive controls. The FDA requires that this analysis is written, regardless of whether it identifies any hazards.
- When the analysis identifies hazards that necessitate a preventive control, the FSP must also include additional written documents:
  - Preventive controls such as:
    - Process controls.
    - Food allergen controls.
    - Sanitation controls.
    - Supply-chain controls.
    - Recall plan.
    - Other controls.
  - Procedures for monitoring the implementation of preventive controls.
  - Corrective action protocols.
  - Verification procedures.



UPGRADE NO. 2

Consider getting some outside help when putting together your FSP. In addition to a host of other services, your local Manufacturing Extension Partnership Program (MEP) can help draft your FSP.

Hazard Analysis

Every FSP must begin with a hazard analysis of every ingredient, process, and manufacturing phase. The FDA defines a "hazard" as any biological, chemical (including radiological), or physical agent that could cause illness or injury. Manufacturers must know that, in terms of food safety, "hazard" refers only to the conditions or contaminants in food that can cause illness or injury to humans.

The hazard analysis includes several components, such as:

- **Hazard identification:** Ascertain any biological, chemical, and physical agents capable of causing adverse health effects that might be present in a food or group of foods.
- **Hazard characterization:** Determine the nature and extent of the adverse health effects known to be associated with the specific hazard.
- **Exposure assessment:** The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources.
- **Risk characterization:** The estimation of the probability of occurrence and severity of known or potential adverse health effects in each population based on hazard identification, hazard characterization, and exposure assessment.

If the hazard analysis fails to identify anything that requires a preventative control, the FSP only needs to include the hazard analysis. However, if the analysis reveals any hazards, preventive controls must be established – and documented – to mitigate potential risks, defined by the FDA as "measures required to ensure that hazards requiring a preventive control will be minimized or prevented."

Regulations insist on these controls for anyone who manufactures, processes, packs, or holds human food. These controls cover:

- **Process controls:** To control parameters during operations. Examples include cooking, refrigeration, and product formulation.
- **Food allergen controls:** To control allergen cross-contact within a facility, including procedures to ensure all food allergens are labeled correctly.
- **Sanitation controls:** To ensure the company maintains the facility in a sanitary manner to control hazards such as environmental pathogens. Regulations require environmental monitoring if contamination of a ready-to-eat food with an environmental pathogen such as Listeria monocytogenes is a hazard requiring a preventive control.
- **Other controls:** Preventive control procedures that aren't process, food allergen, or sanitation controls necessary to ensure a hazard requiring a preventive control will be significantly minimized or prevented.

UPGRADE NO. 3

Regular audits can ensure that the FSP is effective and increase food safety awareness throughout the plant. Share the results with employees to praise strengths and reveal areas of improvement.

Unlike HACCP plans, FSPs must include a Recall Plan for each product for which a hazard requiring a preventive control has been identified.

Source: FDA

Control Monitoring

Food safety monitoring refers to how businesses regularly check to see that food safety hazards remain controlled, employees follow procedures correctly, and comply with food safety regulations. In addition, food safety monitoring seeks to ensure potential threats don't become uncontrolled and result in illness or injury to consumers.

Manufacturers typically employ Good Manufacturing Practices (GMPs) or prerequisite programs to monitor food safety. For example, suppose a company has a policy instructing employees to store allergenic materials separately, away from non-allergenic materials. In that case, the company must implement a check to support compliance with this requirement.

In a HACCP plan, the Critical Control Points (CCPs) are always monitored. In an FSP, preventive controls are only monitored as appropriate to the nature of the preventive control and its role in the facility's food safety system, and some preventive controls that aren't applied at CCPs may not be monitored.

Source: FDA

UPGRADE NO. 4

Digital systems can generate automatic notifications to alert employees when deviations occur. For example, employees can monitor a raw material by verifying the supplier's Certificate of Analysis (CoA) against the material specification. Manufacturers can automate that process by digitizing the incoming CoA and analyzing critical data for material acceptance against specifications. Effective digital solutions can automatically accept or reject the material after comparing CoA data against the material specification. This relieves personnel of a time-consuming task while reducing mistakes.

Corrective Actions

Corrective action plans identify and correct the cause of a deviation to prevent a recurrence. These multistep plans are critical to improving the FSP and ensuring food safety. So, employees must complete every step quickly and thoroughly.

UPGRADE NO. 5

With the right software solution, users can create task-based workflows to assign responsibility, trigger notifications, and document activities for:

- Identifying product non-conformity.
- Evaluating affected product.
- Correcting the non-conformity (including management of corrective action evidence.
- Identifying the root cause and determining actions to prevent a recurrence.
- Verifying corrective action implementation and effectiveness.

In a HACCP plan, corrective actions are taken for deviations from a critical limit at a CCP. An FSP also provides for facilities to take corrective actions. However, immediate corrections (e.g., re-cleaning and sanitizing a line before start-up of production when food residue remains after cleaning) may be more appropriate for some preventive controls than a specific corrective action involving product risk evaluations of product safety for some preventive controls. The requirements for an FSP provide this flexibility.

Source: FDA

Verification Procedures

In a HACCP plan, verification activities take place for process controls to ensure the process can control the hazards and the HACCP plan is being followed. In an FSP, verification activities will also be applied to preventive controls, but because preventive controls are not just process controls, there is flexibility to conduct verification activities as appropriate to the food, the facility and the nature of the preventive control and its role in the food safety system.

Source: FDA

Lastly, users should be able to implement electronically-captured data and a task-based workflow to support verification activities of the FSP. For example, HACCP or HARPC-based plans require scientific or technical evidence — or statistically valid studies — to validate food safety controls. Electronic management of processing data can support the documentation of technical evidence or challenge studies to demonstrate the effectiveness of food safety controls and associated limits.

Food safety plan verification involves:

- Confirming consistent implementation and effectiveness of controls.
- Authenticating monitoring.
- Substantiating corrective action completion and implementation.

Traditional methods for validating the continued implementation and effectiveness of food safety controls include:

- Material and/or product testing.
- Internal audits.
- Environmental monitoring.
- Control-related data trending.

UPGRADE NO. 6

Automating verification tasks through scheduled notifications and task-based management supports a critical component of the food safety plan, which employees can overlook because of the infrequency of these activities. Additionally, electronic data management quickly and effectively supports data queries. Finally, digital verification of corrective actions allows users to efficiently forward supporting documentation to customers, third-party auditors, or regulators.

Embracing a Food Safety Culture

The best way brands can attract and retain customers is by consistently offering high-quality, safe products. However, without standardized procedures in place, such as an FSP, companies can struggle to control the quality of finished goods. If left unchecked, mistakes in the product manufacturing process can lead to significant problems downstream, including costly recalls.

It all starts with companies embracing a food safety culture that goes beyond filling out forms as part of a written plan.

"There are two basic questions that need to be answered for processors, handlers or retailers wishing to implement a food safety culture in their operation," Food Scientist Richard Stier wrote in Food Engineering magazine. "These are: What elements should be included in a company's food safety culture, and how does one go about implementing the program?"

As Stier suggests, this starts with upper management, which is responsible for instituting and supporting a food safety culture.

"Management must establish the necessary food safety policies; provide the funding for training and education, equipment upgrades or new purchases; establish policies for communicating internally and externally; and find the right people to manage not just the food safety programs but to build the culture," Stier explained.

UPGRADE NO. 7

Companies can easily apply consultant Dr. John Kotter's "8-Step Process for Leading Change" to the implementation of a food safety culture at any organization:

1. Establish a sense of urgency.
2. Create a guiding coalition.
3. Develop a vision and strategy.
4. Communicate the change vision.
5. Empower employees for broad-based action.
6. Generate short-term wins.
7. Consolidate gains and produce more change.
8. Anchor new approaches in the culture.

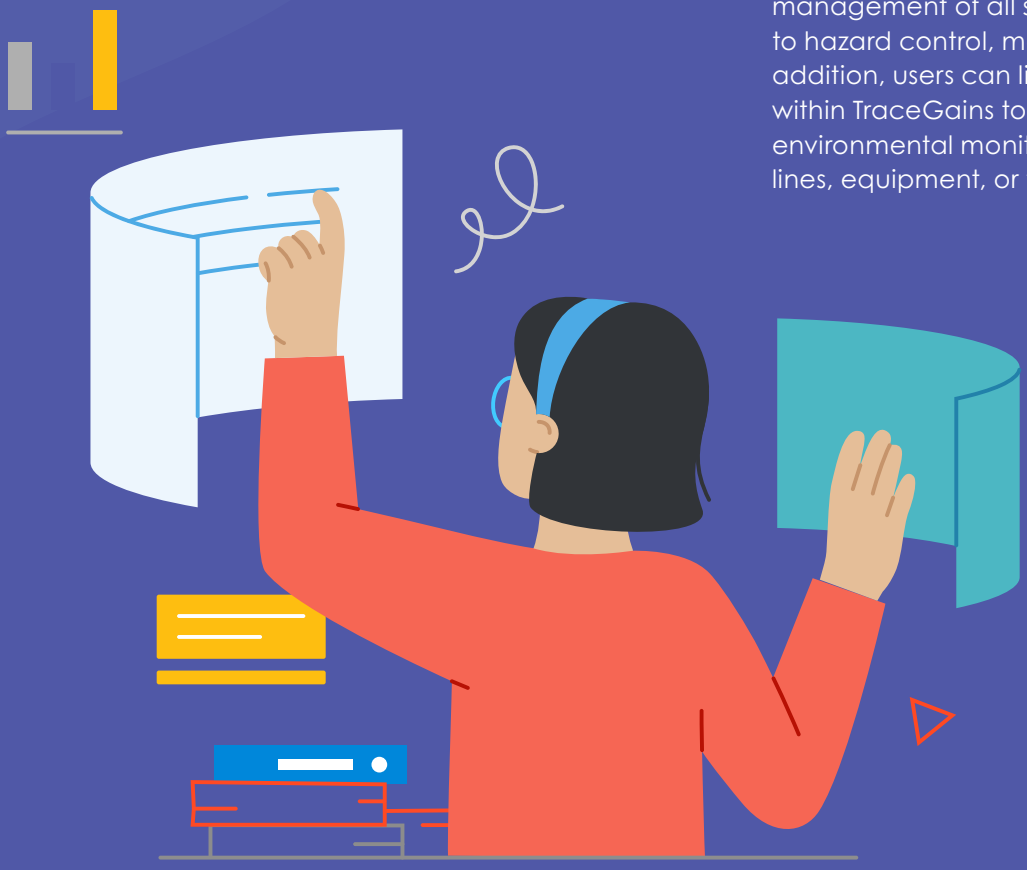
TraceGains Can Help

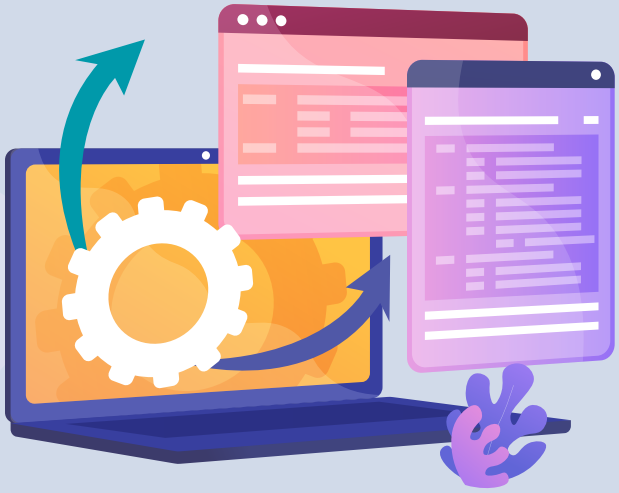
Food safety management software can support proactive, long-term approaches to mitigate food safety threats while encouraging a more robust food safety culture. Monitoring, corrective action, and verification activities commonly drive most procurement, production, and distribution tasks, consuming more personnel resources. Automating these activities by leveraging technology eliminates time-consuming tasks such as manual oversight of workflows, data entry, document management, and record retrieval.

So how can companies automate critical tasks within the food safety plan and sanitation, supply chain, and training programs to maximize personnel resources and improve overall effectiveness?

The TraceGains suite of cloud-based software solutions can help brands better manage FSPs. Automating tasks eases the burden for scheduling, data collection, recordkeeping, and workflow oversight. This frees up resources for successfully identifying, correcting, and preventing the recurrence of food safety control deviations. In addition, TraceGains can help reduce paper, automate business processes, track workflow activities, improve responsiveness through notifications, and help drive continuous improvement through data analytics.

With TraceGains, users can connect the food safety plan activities to trigger a corrective action automatic alert when monitoring results exceed limits. This links the corrective action to one or more production lots associated with the monitoring activity for efficiency in identifying and managing non-conforming product. Scheduling sanitation tasks and tracking completion in TraceGains can be executed for both Clean-in-Place (CIP) and Clean-out-of-Place (COP) activities for congruent management of all sanitation activities related to hazard control, monitoring, and verification. In addition, users can link sanitation tasks completed within TraceGains to pre-operational inspections and environmental monitoring results through production lines, equipment, or facility areas.





Digitize CoAs

TraceGains can extract CoA data for materials received followed by linking material results to individual production lots and batches, which the system traces through to distribution. This supports increased transparency, the chain of custody, and material trending while reducing the burden on personnel for collecting and managing CoA data. In addition, companies can improve the efficiency and accuracy of supplier compliance through the automatic determination of out-of-spec results and corresponding notifications.

Streamline Supplier Management

Once suppliers are selected and approved, TraceGains can track supplier and material performance from order placement and receipt through third-party testing and material use. In addition, users can apply business rules to evaluate materials against specifications with auto-corrective action features to engage supplier investigations and feedback.

Co-Author Specifications with Suppliers

Specification Management allows companies to draft, publish, and update raw material and finished goods specifications. Specification Management streamlines and centralizes documentation and information exchange with automated workflows and alerts for internal and external stakeholder updates and approvals. With network connectivity, the software gives companies immediate access to more than a million supplier-provided documents to accelerate specification creation and updates. Companies can choose which suppliers can access shared specifications, allowing them to author or edit, review read-only sections, add comments, attach documents, negotiate attributes, and approve or decline specifications, with all correspondence and agreements tracked digitally.

Automated Oversite of Food Safety Training

When it comes to training, TraceGains can provide automated oversight of food safety training programs through:

- Electronic documentation and management of competencies.
- Automatic notifications to area supervisors or managers of staff training needs.
- Tracking of training completion.
- Electronic recordkeeping of knowledge assessment results with auto-alerts for continued training needs.

About TraceGains

Founded in 2008, TraceGains connects people and information so teams can work smarter. As a global technology company, we provide networked innovation, quality, and compliance solutions to consumer brands that want to reduce supply chain risk, speed up business processes, and take control of data. On average, companies find 80% of their suppliers already on TraceGains Network, allowing them to connect and collaborate instantly.

The Power of TraceGains Network

TraceGains Network is where professionals in R&D, procurement, quality, and regulatory departments connect with suppliers and co-manufacturers to bring new products to market faster safely. Thousands of supplier locations and data sources are combined to identify and qualify new vendors, precisely source raw materials, items, ingredients, packaging, and services, request samples, negotiate specifications, and automatically collect supporting documentation.