



# An Overview Of Regulatory And Food Safety Programs For The Farm-to-table Supply Chain

## EXECUTIVE SUMMARY

Food processors, distributors, logistics firms and other organizations in the farm-to-table food chain are challenged to establish food safety programs to ensure compliance with stringent laws and regulations.

Provided is a thorough overview of current regulations, with an explanation of the role of schemes to organizations within the food chain.

**This paper serves as a guide for companies to understand the regulatory landscape, and the best practices to obtain and retain desired food safety certification schemes.**



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# Overview of Regulations and Explanation of the Role of Schemes

U.S. federal law divides the food processing sector into two broad categories: meat and poultry which is overseen by the Food Safety Inspection Service (FSIS) of the USDA and all other food processors as overseen by the U.S. Food and Drug Administration (FDA). Typically FDA FSMA is thought of as the first level of priority as meat/poultry and agricultural products are subsequently processed into final products under FDA.

The food processing sector includes the processing, warehousing, and transportation of food. Pet food, animal, as well as livestock feed are also subject to similar sanitary regulations.

Within the FDA, The Center for Food Safety and Applied Nutrition (CFSAN) focuses on human food and The Center for Veterinary Medicine (CVM) is responsible for animals. Within Canada the Canadian Food Inspection Agency's Safe Food for Canadians Regulations (SFCR) is dedicated to the safeguarding of food, plants, and animals. Mexico's equivalent of the FDA is COFEPRIS under the general Official Mexican Standards or Norms (Normas Oficiales Mexicanas—NOMs).

## *U.S. Legislation Overview*

There have been a variety of congressional acts, including the Food Safety Modernization Act (FSMA), that regulate the United States Food Chain.

These acts are codified into law in the Federal Register which contains the Code of Federal Regulations (CFR). There are three titles relevant to the Food Chain safety. Title 7 – Agriculture, Title 9 – Animals and Animal Products, and Title 21 – Food and Drugs.

These titles are divided into parts. For example, a regulation classified as updated under FSMA 21 CFR part 117 relates to sections within the Federal Regulations which describe "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food."

## ***Global Industry Mandates***

Independent of government mandates, a global food safety standard emerged called the Global Food Safety Initiative (GFSI). GFSI is a non-profit foundation sponsored by The Consumer Goods Forum based in Belgium that benchmarks existing food standards against food safety criteria. GFSI develops mechanisms to exchange information in the supply chain, raises consumer awareness about safety, and reviews existing standards for good retail practices of safe foods and products.

GFSI does not provide food safety certifications but establishes standards for recognized certification Schemes that meet the GFSI requirements. These certification programs (or schemes) that are approved and benchmarked under GFSI include:

- **SQF**
- **FSSC 22000**
- **IFS International Featured Standards**
- **BRCGS**
- **primusGFS**
- **Global GAP**

## ***Compliance and Audits***

There are a variety of schemes including SQF, FSSC 22000, BRCGS and IFS Food that when implemented, significantly ensure that organizations comply with FSMA and GFSI. If the scheme is successfully implemented, you and your customers can be sure you follow laws and the GFSI standard.

The FDA, USDA, and CFIA require registration of all food processors. Under their jurisdiction, these organizations conduct food safety audits.

Audits are both announced and unannounced. When auditors find practices or conditions that are not in compliance with the regulations, they issue “non-compliance” findings.

Depending upon the severity of the non-compliance findings, penalties up to criminal prosecution can occur. Because inspections may occur at any time, today’s food processors must have an ongoing food safety program. The food safety schemes under GFSI, like SQF, provide the guidelines on how to design and implement food safety programs.



The schemes ensure compliance in the following areas required under FSMA:

- **Federal Registration**
- **PCHF/AF, Hazard Analysis and Critical Control Point (HACCP) Food Safety Plan**
- **Food Defense Plan to prevent Intentional Adulteration of Food Product**
- **cGood Manufacturing Practices (cGMPs/PRPs/SSOPs)**
- **Standard of Identity reflected properly on labels – Labeling Under the various Regulations**
- **Rules for Food Additives and GRAS (Generally Recognized as Safe or otherwise approved)**
- **Color Additives and other related ingredients**
- **Supplier Qualification and Verification**
- **Plant Controls of Contact Surfaces, Water, Air and Environment**
- **Packaging and Labeling**
- **Nutritional Content, Servings Size and Health Claims**
- **Product Traceability, Recall and Recall Plan**
- **Record Keeping Retention**
- **Employee Training – Fully Documented and Evident**
- **Food Imports and Exports – FSMA Foreign Supplier Verification**
- **Reportable Food Registry**
- **The National Outbreak Reporting System (NORS)**
- **Enforcement Jurisdiction**

## **Project Planning and Scheme Selection**

It is not realistic for a typical food processor to track the vast number of pages in the Federal Register and then independently take the steps necessary to comply. The market leading processors look to knowledgeable resources to review relevant food safety schemes.

Food safety program review should start with management commitment, a proper steering team and cross functional implementation.

The next step is to tailor the food safety program plan to an organization's determined process and product risks and needs, the desired food safety scheme(s), and meeting customer requirements.

***Food safety plans should consider organizational issues and create a model to address all business requirements.***

The plan should address organizational issues and create a model to address all required areas and processes with a focus on compliance to food safety, regulations, supply chain and customers.

## ***Suggested Steps to Certification***

Adroit sees the following as key steps toward obtaining a certification:

- 1. Access and align requirements via an online download or access to the standard**
- 2. Determine what is required for the food safety management system for food companies and processors**
- 3. Designate the process to train your Food Safety Team Leaders**
- 4. Design, document and implement the required processes and programs within the framework of your business model**
- 5. Train your internal audit team**
- 6. Run your system, collect records, perform internal audits, management review and Food Safety Team/HACCP team meetings.**
- 7. Make correction actions and continuous improvement to your system.**
- 8. Select a certification body**
- 9. Provide process and monitoring to schedule and complete your audits**

# Food Safety Assessment

We have seen processors be successful when they conduct a thorough review of current practices and procedures to identify those areas that would be flagged as non-conformance by the FDA / USDA / CFIA.

This assessment serves to create a gap report flagging the requirements under the targeted scheme such as SQF and the other food safety schemes, and a gap report tracking specific customer requirements. When built effectively, the report should highlight serious issues and provide stop gap recommendations ahead of the full program development.

## Program Development

Effective food safety programs should consider the various areas of the food safety scheme and typical customer requirements to provide complete evidence of the areas that require formalized processes, procedures, and systematic record keeping. We are a strong advocate for the integration of business procedures and systems and food safety procedures and systems.

Successful development of a food safety program incorporates electronic records, electronic signatures, and procedures which are facilitated by the business or ERP system. Control points are flagged/stamped in workflow for documentation. Exceptions are captured in the system. Lot traceability and recalls are facilitated through the system.

By integrating the systems, processors are in a position to produce proof of compliance and recalls very rapidly to stay within regulatory standards. Manual systems and paper records are not scalable nor are they effective document management system. Yet even today, many organizations rely on paper-based binders corresponding to the sections of the compliance scheme such as the following:







***Food safety compliance is no longer just a “quality” team problem. It is a business problem.***

## ***An Effective Safety Framework***

Today’s market leading organizations put the focus on more than achieving the bare minimum of compliance. Instead, these organizations establish a responsive and systematic framework that will scale with the business and provide real time metrics that provide compliance assurance.

Food safety compliance is no longer just a “food safety and quality” team problem. It is a business and enterprise risk problem.

The best-practice approach is to develop detailed policies and procedures, utilizing system automation and electronic signature capture where possible, that when implemented will position the processor to pass and remain in compliance of FSMA and GFSI and pass the food safety scheme audit.

## *Training and Implementation*

A best practice approach to food safety plans puts emphasis on both on-premise and remote training programs. The training can be part of a full food safety program or targeted to problematic areas that are part of a non-compliance concern.

Trainers should provide, review, and demonstrate specific procedures with all the organization's teams.

It is important to identify champions and FSQA or PCQI leads for the procedures and certify them to train company employees, contractors, and all stakeholders.

A useful approach is to create a training matrix based on level, role, and food risk and develop training curriculum and procedures by role. Ensure the training and any changes are implemented and that continuous feedback and metrics are in place to ensure ongoing compliance.

Best-in-class processors take additional steps when implementing and maintaining food safety programs, including:

### ■ **Teaming with External Resources for Audit and Inspection Preparation:**

An organization anticipating an upcoming audit rarely has the time or resources needed to manage the effort. Companies are effective when they team with an expert resource to walk through policies, procedures, records, and exception management. This review helps leaders understand where they may have potential deviations. Experts can then help to correct those deficiencies to give the confidence that the organization will perform well for the audit or inspection.

### ■ **Program Development, Audit, and Non-Conformance Support:**

It is also valuable to work with experts onsite during the audit or inspection to help communicate current policies, procedures, and record meaning and to help to answer questions or concerns. Where the audit or inspection raises unexpected deviations, experts can help correct exceptions rapidly and effectively facilitate with the auditor or inspector.



# Food Safety Certifications

The myriad of food safety certifications can be confusing and a bit overwhelming.

Noted here is an overview of safety certifications. By being aware of the regulatory landscape, organizations are better able to pursue the correct certification for their industry.

***An awareness of the regulatory landscape makes organizations better able to pursue the correct certification for their industry.***

## SQF

The Safe Quality Food (SQF) Program is a rigorous and credible food safety and quality program that is recognized by retailers, brand owners, and food service providers world-wide. Recognized by the Global Food Safety Initiative (GFSI), the SQF family of food safety and quality codes are designed to meet industry, customer, and regulatory requirements for all sectors of the food supply chain – from the farm all the way to the retail stores. Their website is [sqfi.com](https://www.sqfi.com).

## BRC

The British Retail Consortium (BRC) is a trade association for the UK food retail industry created in 1992. The BRC has published standards for best practices for the food and manufacturing industries for two decades and publishes the On-Pack recycling standards for the UK. The BRC Global Food standard has been in existence since 1998, and in 2000 was the first food safety standard to be recognized by the GFSI organization, which means the standard meets their “benchmark” criteria for acceptance. The standard is designed as a “total quality management” program and includes both food safety requirements and quality requirements which food manufacturers must meet to be certified. Their website is [brcgs.com](https://www.brcgs.com).

## **FSSC 22000**

FSSC 22000 is a Food Safety Management Certification Scheme, managed by Foundation FSSC 22000 and governed by an independent Board of representatives from several sectors in the food industry. FSSC 22000 is used to control food safety risks.

Developed through extensive and open consultation with many global stakeholders, the Scheme uses international and independent standards such as ISO 22000, ISO 9001, ISO/TS 22003, and technical specifications for sector-specific Pre-Requisite Programs (PRPs), such as ISO/TS 22002-1. Besides these standards, the Scheme contains so-called FSSC Additional Requirements, which can be found in the FSSC 22000 Scheme documents.

Through meeting the Global Food Safety Initiative (GFSI) Benchmarking Requirements, the FSSC 22000 Scheme has been given full recognition since 2010. GFSI recognition demonstrates that the Scheme meets the highest standards globally, leading to international food industry acceptance. Furthermore, the Scheme is widely accepted by Accreditation Bodies worldwide and supported by essential stakeholders like FoodDrinkEurope (FDE) and the Consumer Brands Association (CBA).

## **IFS**

IFS-The IFS Food Standard is a GFSI (Global Food Safety Initiative) recognized standard for auditing food manufacturers. The focus is on food safety and the quality of processes and products. It concerns food processing companies and companies that pack loose food products, distributes foods, and manufactures food packaging.

IFS was a foundation scheme for GFSI and originally centered on the major global retailers based in France, Germany and Central Europe.

## **ISO 28000**

ISO 28000 was developed to establish standards and procedures dealing with supply chain security. It focuses on security management policies, security risk assessments and planning implementation and operation, checking and corrective action, and continuous improvement. The website for the standard is <https://www.iso.org/standard/44641.html>.

## **cGMP/GMP/HARPC/HACCP/GAP**

A Good Manufacturing Practices certification scheme provides independent verification and certification that basic manufacturing practices necessary for an effective Hazard Analysis Critical Control Point food safety program are being followed. HACCP is a subset of an overall food safety program. A GMP certification can be an important step towards a broader food safety program certification.

# Integrated Food Quality and Food Safety Systems for Effective Compliance

The summary provided above serves as a high-level overview of the complicated food safety regulatory landscape.

***Today's leading food processors integrate food processing, regulatory, and compliance as a single information system.***

Food processors, distributors and logistics companies are continually confronted with increasing burdens of food safety record keeping as the FDA, USDA, and CFIA and the GFSI work to drive food safety towards prevention in addition to reaction.

The most effective processors integrate food processing, regulatory, and compliance as a single information system.

When the regulatory or compliance record keeping is paper based or separate from the Enterprise Resource Planning (ERP) and Manufacturing Execution System(MES) it creates an environment where traceability and required controls are missed.

If the compliance system is built into the process step, then control points can be enforced as a prerequisite to the completion of the purchase receipt, material issue, temperature setpoint, shipment, and other areas.

Stand-alone or siloed traceability and food recall systems cannot effectively provide the speed and granularity necessary to execute recall within required time frames. The scope of recall will be much larger and the costs more extreme.

A best practice approach relies on expertise from resources familiar with Enterprise Resource Planning (ERP), Warehouse Management (WMS) Transportation Management Systems (TMS) and Food Safety systems.



Processors that team with industry-specific advisors move their compliance schemes into an integrated and workflow driven framework. This approach lets company reduce ongoing record keeping costs, speed record access, and ensure higher levels of compliance and food safety.



## *Adroit Food Safety Compliance Programs*

Adroit serves as a food safety training and systems integration organization. We assist food processors, distributors, logistics firms, and other organizations in the farm-to-table food chain.

We establish food safety programs that are integrated with your business processes to ensure compliance to laws and regulations while eliminating systems and record keeping redundancies.

Learn more at [adroitna.com](http://adroitna.com).