



Food Safety and Quality Regulations: A Guide to Global Standards

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Food Safety and Quality Regulations: A Guide to Global Standards

Navigating today's regulations on a local, national and global level is complex and time-consuming. The sheer number of regulations and recommended standards, the overlap between them, the nuances that impact day-to-day operations and required deadlines can be overwhelming for any company in the food and beverage business, especially mid-sized and smaller organizations. The acronyms alone can be head-spinning.

Adding to the complexity of industry requirements and suggested voluntary actions is the ongoing move toward globalization. It's not enough for U.S. manufacturers to be well versed on federal and state guidelines or, for that matter, what's required for exports and imports. As more companies are part of international organizations or have offices or a presence in other countries, the need for learning and heeding different standards is growing along with expanded business. What is mandated in one part of the world impacts work done in other parts of the world.

Globalization and the overall need to demonstrate a strong [food safety culture](#) has propelled companies throughout the supply chain, including food and beverage manufacturers as well as food service operators and retailers, to commit to more stringent practices for safety and quality. At the same time, end consumers are increasingly interested in knowing

where their consumable products come from—and knowing that those items have been produced in a safe manner.

Given the consequences, ranging from fines to recalls to litigation to lost business, manufacturers must be up to speed on what's required and how to stay compliant. On the positive side, being in line with requirements is also a competitive advantage in assuring safe, high quality, satisfying products and in preventing costly recalls.

The task and challenge is to engage key personnel to know and understand the relevant standards and how to stay compliant. Referencing information on regulatory and voluntary standards, such as this guide, can help address challenges and accomplish the goal of successful adherence to important requirements and certifications on all scales.

1. Regulatory Overview

There are several food safety standards in place that impact individual companies. Depending on the location and type of business, a manufacturer may be guided by dozens of standards, regulations and/or laws.

That said, there are important globally recognized food safety standards that affect most manufacturers' operations in some way.

A. International Organization for Standardization (ISO) 22000: - ISO is an independent organization that includes 161 national standards bodies, and works through its members to develop voluntary "market relevant" international standards that provide solutions to global issues. The relevant standard for food safety management within ISO—which is also pivotal as the trend toward globalization continues—is the ISO 22000.

The ISO 22000 family of standards is designed to help manufacturers identify and control food safety hazards, including (but not limited to) contaminants. A core of the standard is the deployment of a food safety management system (FSMS), a strategy for creating and maintaining a food safety program in compliance with pertinent local, national and global standards. Per the ISO 22000 standard, a FSMS should be based on HACCP principles to control hazards and should also include the documentation of comprehensive food safety procedures. Training programs are central to the ISO 22000 standards, as are clearly defined food hazard levels.

The standard also shows manufacturers how to combine HACCP plans with prerequisite programs and operational prerequisite programs into an integrated food safety strategy. In fact, the most recent revision to the ISO 22000 was in June 2018, with changes including a different approach to understanding risk and a clarification on differences between critical control points (CCPs), Operational Prerequisite Programs (OPRPs) and Prerequisite Programs (PRPs).

B. Hazard Analysis Critical Control Point (HACCP): As the name implies, the [Hazard Analysis Critical Control Point](#) (HACCP) system focuses on key points of vulnerabilities or critical control points for hazards within various steps in the production process. In the U.S., HACCP regulations were first implemented by the Food and Drug Administration (FDA) and Food Safety

Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) beginning in the late 1990s. Today, the science-based HACCP system is an internationally-recognized approach to identifying hazards and measures to ensure food safety. HACCP focuses on measures and methods to prevent hazards, such as contaminants from moving through the chain.

The seven principles of HACCP:

- Conduct a hazard analysis.
- Identify critical control points (CCPs).
- Establish critical limits for critical control points.
- Establish monitoring procedures.
- Establish corrective actions.
- Establish verification procedures.
- Establish record keeping and documentation procedures.

C. Codex Alimentarius: Codex Alimentarius is a collection of globally recognized standards and guidelines and codes of practices that are referenced in several national food safety standards. This food code was developed by the Codex Alimentarius Commission, a joint venture between the Food and Agricultural Organization (FAO) of the United Nations and the World Health Organization (WHO).

Contaminants that could threaten human health are addressed in the Codex Alimentarius, which establishes a maximum level for contaminants in food: the threshold is 17 (MLs) for contaminants defined as "substances that have not been intentionally added to food." The Joint FAO/WHO Expert Committee on Food Additives evaluates contaminants in food twice a year.

D. Global Food Safety Initiative (GFSI): GFSI, created by private organizations in 2000, is designed to improve food safety management programs through various benchmarking requirements that are broad yet relevant enough to translate across different countries and regions. GFSI benchmark requirements recognize certain food safety management schemes that fulfill criteria as set forth in its regularly updated GFSI Guidance Document.

The following good safety certification programs (formerly referred to as "schemes" by GFSI) are recognized by the GFSI:

- BRC Global Standards for Food Safety
- FSSC 22000 (ISO 22000, 2018. Pre-requisite: ISO/TS 22002-1:2009, FSSC22000 additional requirements: Part II 2.1.4)
- SQF (7th Edition and 8th Edition)
- IFS International Featured Standards
- Global Red Meat Standard
- Canada GAP
- Japan GAP Foundation
- Japan Food Safety Management Association
- Global Aquaculture Alliance
- GlobalG.A.P
- PrimusGFS Standard

Being certified to GFSI's benchmark standards demonstrates an organization's serious commitment to food safety to customers and potential customers across the world.

- E. British Retail Consortium (BRC) Global Standard for Food Safety:** As the first food safety standard to be recognized by the GFSI in 2000, the [BRC Food Safety Standard](#) is a total quality management program for food safety and quality. It was developed by the British Retail Consortium (BRC), a trade organization for retailers in the United Kingdom, and is now used as standard around the world. The newest standard, Issue 8, came out last year: the standard maintains fundamental components like HACCP plans but includes new and updated elements, such as a greater emphasis on improving an organization's food safety culture, more stringent requirements for environmental monitoring, and clarity on requirements for high-risk production zones, among other changes.
- F. International Featured Standards (IFS):** IFS is another standard for food production and processing that is recognized by the GFSI benchmarking requirements. An important standard in Europe, IFS is also being used more often around the world because it establishes a common standard with a uniform evaluation system for suppliers throughout the supply chain. The scope of requirements includes Senior Management Responsibility, Quality and Food Safety Management Systems, Resource Management, Planning and Production Process, Measurements, Analysis and Improvements, and Food Defense. Audits are part of certification

to the IFS, covering safety and quality, and companies can use the IFS logo and certificate to demonstrate their compliance with this high uniform standard.

- G. Safe Quality Food (SQF) Program:** Created by the SQF Institute to control food safety risks, the SQF program is a food safety management certification scheme that is recognized around the world by manufacturers, retailers and food service operators. It covers the whole farm-to-fork supply chain with a separate standard that assesses product quality. Exemplifying some of the overlap of food safety standards, the SQF program fuses protocols for HACCP and ISO 22000. SQF certification is also a recognized GFSI standard. The difference is that SQF covers both safety and quality simultaneously; the combination of both elements is one reason why many companies seek SQF certification.

1.2 In the U.S: Food Safety Modernization Act

On the books since 2011 in the United States, the [Food Safety Modernization Act \(FSMA\)](#) is designed to prevent food safety hazards, including the spread of contaminants, and to improve the detection of and response to food safety problems. The law is enforced by the U.S. Food and Drug Administration (FDA), which can now order recalls if the agency believes food is contaminated or poses a hazard. This reflects a shift in mindset and approach from reacting to food safety crises and problems to preventing them.

Food manufacturers in the U.S. must comply with general FSMA requirements, including registering with the FDA on a biannual basis, creating a food safety plan with preventive controls based on hazard analysis (where HACCP fits in), creating a food defense plan and properly reporting foods that can cause "adverse health effects."

The implementation of the FSMA in the U.S. has affected HACCP plans, in that prerequisite programs (PRPs) are deemed as important as critical control points, and now fall with CCPs under the broader umbrella of preventive controls. While a critical control point refers to steps in the process that can involve controls, PRPs are safety—and hygiene—related procedures addressing conditions that are foundations for HACCP that can include sanitation, supplier control and training, among other elements.

1.3 Legislation and Regulatory Agencies in Other Regions/Countries:

In addition to global organizations that issue and oversee standards and accompanying certifications, individual countries have their own agencies, regulatory bodies and food safety laws and regulations that impact food and beverage production in those areas.

Canada: The Safe Foods for Canadians Act was passed in 2015 to improve the country's food safety system by consolidating authorities of various food-related statutes into a single act. The Canadian Food Inspection Agency oversees food safety.

EU: The European Food Safety Authority (EFSA) is an independent agency that provides scientific advice and support for EU laws that impact food safety.

UK: The Food Standards Agency is an independent food safety department that protects food safety within the United Kingdom.

Australia/New Zealand: Food Standards Australia New Zealand is a governmental body that develops food standards for Australia and New Zealand based on scientific assessment of risk to public health.

China: In China, the State Food and Drug Administration was created to consolidate food safety regulations. The Peoples Republic of China's Food Safety Law was passed in 2015 to protect public health, and covers organizations that produce food within the country.

Japan: Food safety in Japan falls under the jurisdiction of the Department of Food Safety within the ministry of Health, Labor and Welfare and is based on the Food Safety Basic Law, passed in the early 2000s.

India: Part of Ministry of Health and Family Welfare, the Food Safety and Standards Authority of India was established under the Food Safety and Standards Act of 2006.

1.4 For all of the above: Good Manufacturing Practices as a Foundation for Safety and Quality

Good Manufacturing Practices (GMPs) are the proverbial building block of all food safety programs that are ultimately compliant with global, regional, national and local regulations and standards. In

principle, GMPs, which are accepted worldwide, include practices, systems and controls for making safe, high quality products that are produced, packaged and stored under hygienic conditions. GMPs, along with Standard Operating Procedures (SOPs), are part of HACCP plans and ISO 22000 standards. GMPs are formally written into food regulations in the U.S. by the FDA.

While they are fundamental in safety and quality programs, GMPs are also an assurance to a manufacturer and its customers that the organization has measures in place to produce and deliver safe products.

2. Compare and Contrast for Compliance

The depth and breadth of global food safety standards may be intimidating for those putting plans in place for safety, quality assurance and compliance, but many of the schemes are designed to be integrated into others for more streamlined compliance and a simpler certification and audit process. The overlap, in some cases, is intentional.

Here are some examples of some of the overlap and integration:

- GMPs are a prerequisite for HACCP and a basic part of ISO 22000 standards
- Codex Alimentarius are part of FSMS integrated into ISO 22000
- HACCP is integrated into ISO 22000
- BRC and SQF are recognized by GFSI
- HACCP and ISO are integrated into SQF programs

2.1 Audits

[Audits](#) are a part of operating under and abiding by regulations and standards. In the U.S., food and beverage plants may be subject to audits by the U.S. FDA and USDA, among other regulatory agencies. As part of certification to the GFSI food safety standards, such as BRC, SQF and IFS, companies also can be audited, usually by third party certification bodies. Audit timing, frequency, and requirements vary.

3. Key Internal Systems for Compliance

Manufacturers following requirements and standards for food safety and quality have certain food safety protocols and practices in place internally to make sure they are aligned with what's expected

and required of their operation.

Those protocols and practices include, but are not limited to:

- A. **GMPs:** A foundation for other food safety protocols, GMPs encompasses methods, systems, facilities and controls in the production of safe, high quality foods and beverages. GMPs are typically included in food regulations.
- B. **SOPs:** Written practices and procedures that include details on how foods or beverages are produced safely within a facility or company.
- C. **Prerequisite Programs (PRPs):** Since the passage of the FSMA, PRPs in the U.S. have the same weight as critical control points (CCPs). PRPs can include Operational Prerequisite Programs (OPRPs), with control measures that help prevent significant hazards.
- D. **HACCP Plans:** Science-based HACCP plans are in place to identify and prevent hazards, including contaminants that pose food safety risks. Diligent record keeping is part of HACCP, which helps with demonstrated compliance and also shows a company's customers that the organization is serious about food safety and quality.

- E. **Food Safety Management Systems (FSMS)** are part of an organization's management system and has all of the elements to ensure food safety by:

- Reducing the occurrence of food safety related incidents
- Minimizing the likelihood of contracting food borne diseases
- Ensuring compliance to Food Safety legislation
- Building a Food Safety performance into the supply chain
- Establishing your organization as "safe food manufacturer"
- Qualifying you as a global food supplier
- Ensuring customer confidence through the use of hazard controls
- Assuring that food safety culture becomes organizational culture

The best way to build a food management system is taking the steps to achieve ISO 22000 certification.

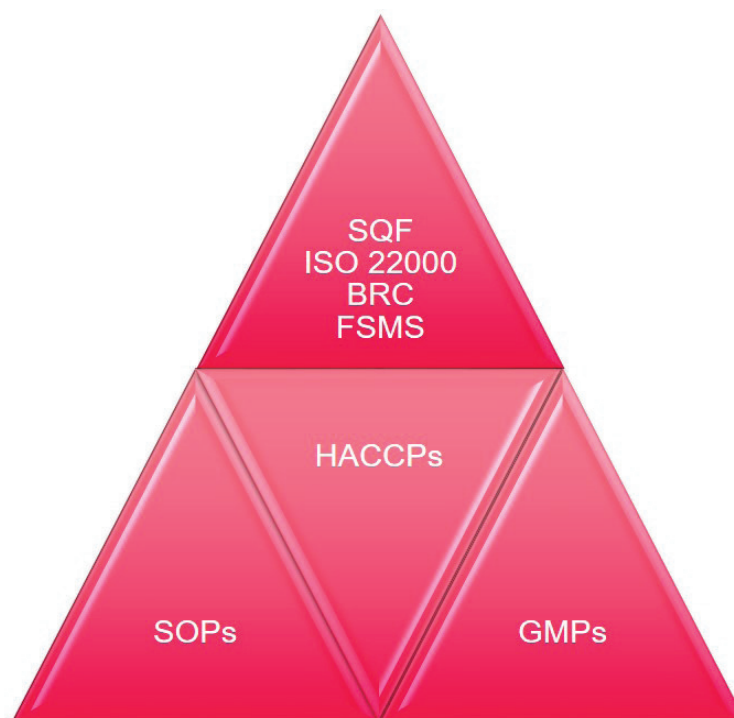


Figure 1: Pyramid of Food Safety Standards

4. How Detection Technologies are an Important Tool in Regulatory Compliance

As manufacturers implement food safety practices to stay compliant with regulations and standards, they have tools at their disposal to prevent hazards and demonstrate their strong food safety commitment and programs.

As a technology that detects and rejects physical contaminants and is also used to ensure product integrity, x-ray is a crucial part of food safety programs. X-ray systems are a fundamental element of GMPs and, moving up the pyramid of dependencies, in HACCP, SQF, ISO 22000 and FSMS, that in turn are approved by and compliant with GFSI and government/regulatory bodies.

- A. **HACCP:** X-ray systems are installed at critical control points (CCPs), from the assessment of raw materials in the beginning of the process to a final check of the package before a shipment leaves a facility. Installing x-ray systems along the line stops hazards earlier in the process before they cause problems down the line.
- B. **SQF:** X-ray systems are also used to perform important quality checks, like component count, mass measurement, fill level, package integrity and more. By maximizing x-ray systems for both contaminant detection and quality control checks, food and beverage manufacturers can check off both safety and quality interventions.
- C. **Traceability:** [Detection systems](#) that are paired with advanced image analysis [software](#) can deliver better traceability. Images and data are captured at the point of inspection and stored in a central database; information can be accessed in real-time or retrieved later in the event of a safety-related question or problem. Having systems in place with traceability is also an important demonstration to food safety during an audit by a regulatory body or third-party auditor on site to certify an organization to a particular standard or standards.

5. Conclusion

With so much at stake in the multi billion-dollar global food trade, producing safe food in a competitive international marketplace means being familiar and compliant with food safety standards and regulations. While seemingly complex, many of these standards and schemes are integrated in a way to facilitate compliance within and beyond a particular country. Preventing hazards is at the heart of all food safety schemes, which requires diligence at the point of production that includes robust inspection capabilities like advanced x-ray technologies with accompanying data-rich software. The constant in the food chain is change, as regulations are frequently updated or added to: having advanced inspection systems in place that focus on hazards is crucial to adhering to past, present and future standards. By partnering with inspection experts with a presence around the globe, such as Eagle Product Inspection, food and beverage manufacturers can stay compliant and competitive on a continual basis.

6. Additional Resources

British Retail Consortium (BRC)
www.brcglobalstandards.com

Foodsafety.gov www.foodsafety.gov

U.S. Department of Health and Human Services
www.hhs.gov

Global Food Safety Institute
www.mygfsi.com

Global Food Safety Resource
globalfoodsafetyresource.com/food-safety/

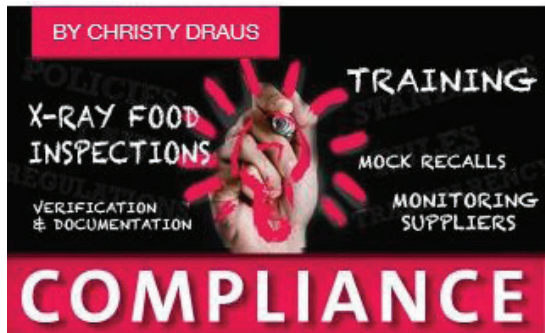
International Organization for Standardization
www.iso.org

North Dakota State University
www.ndsu.edu

SQF Institute www.sqfi.com

U.S. Food and Drug Administration
www.fda.gov

U.S. Food Safety and Inspection Service
www.fsis.usda.gov



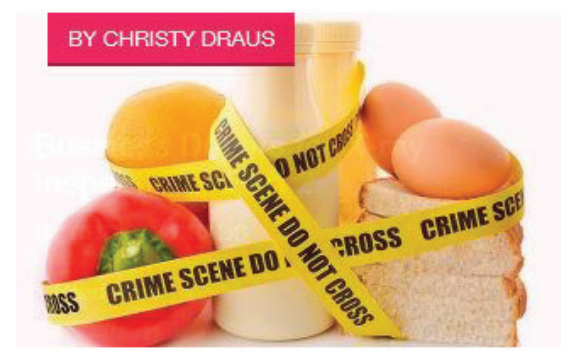
[Compliance Checklist: What You Need and How to Do It](#)



[Are You at Risk for a Recall? Determine Your Points of Vulnerabilities](#)



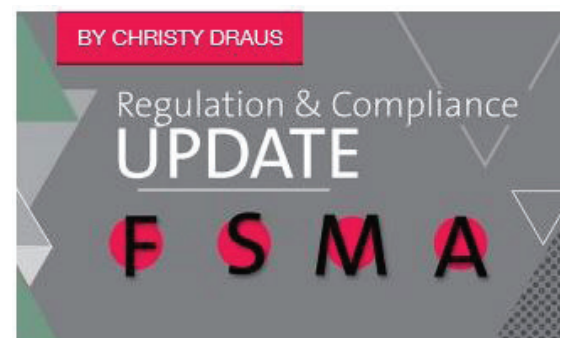
[New BRC Mandates that Impact Food Safety Mindsets and Measures](#)



[Business Drivers for X-ray Inspection Part 2 – HACCP Audits & Identifying Risks](#)



[Eagle's Five Steps to Radiation Safety](#)



[Food Safety Regulation and Compliance Update – What You Need to Know](#)

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[BRC Global Standard for Food Safety](#)



[BRC Issue 8: Creating a Food Safety Culture](#)



[How to Select Critical Control Points for X-ray System](#)



[How to Guide: BRC Audit for Fresh Produce Food Safety](#)



[How to Prepare for a BRC Audit for Food Safety: A Step-by-Step Guide](#)



[Meat Supply Chain: A 'How to' Guide for BRC Audits](#)

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