The Alphabet Soup: The Components that Provide Assurance of Food Safety in Our Food Supply

In the ever-evolving landscape of efforts to ensure the integrity of our global food supply chain, it is important to have an understanding of the elements corresponding to regulatory and non-regulatory aspects of food safety management.

In the 1960's, the United States (US) National Aeronautics and Space Administration (NASA) drew on expertise from Pillsbury Company (now General Mills) to develop a systematic approach to ensure the safety of foods for astronauts in the space program. Today, we know this as the Hazard Analysis and Critical Control Points (HACCP) approach. HACCP has been globally adopted by governments and standards-setting bodies worldwide, including Codex.

1. Food Standards

a. *The Codex Alimentarius Commission*[1] (CAC) is an intergovernmental standards-setting body that was created to protect the health of consumers worldwide and ensure fair practices in international food trade. The CAC sets food standards, codes of practice and guidelines that are referred to as the Codex Alimentarius (or simply 'Codex').[2]

Today, Codex standards are globally used. Cognizant of the rapidly evolving global food markets, challenges around international trade and risks to the food supply, most countries around the world model their food safety management systems around the Codex principles of food hygiene, which recommend HACCP as essential to ensuring the safety and suitability of food for human consumption. Countries may elect to adopt more stringent requirements into their own laws and regulations if they can base their rationale on scientific and risk-based principles (Appendix B).

b. The *International Organization for Standardization* (ISO), which is another international standards development body.

ISO has developed a standard specific to food safety; ISO 22000.[3] It is a voluntary measure that integrates the HACCP system as described by Codex, along with three other elements in a systems approach:

- Interactive communication
- Prerequisite programs
- System management

Historical Timeline of Selected Food Safety Management Systems

1960's	NASA and Pillsbury first develop HACCP (only 3 principles)
1992	NACMCF* introduces 7 principles of HACCP
1993	Codex issues first HACCP guidelines
1994	Safe Quality Foods (SQF) formed
1998	British Retail Consortium (BRC) formed
2000	Global Food Safety Initiative (GFSI) formed
2003	International Food (now Featured) Standard (IFS) created
2005	ISO 22000 Food Safety Management System formed
2008	Food Safety System Certification (FSSC) 22000 created

2. Food Regulations

At the national level, most countries have developed and enacted a regulatory framework around food safety (Table 1).

In the US, two main federal agencies regulate this space:

- The Food and Drug Administration (FDA) and
- The Department of Agriculture (USDA)

> Introduced in 1938, the Food, Drug and Cosmetic Act (FD&C) provided the FDA with authority to oversee the safety of food, drugs, medical devices and cosmetics.[4] In 2011, the most significant amendment to the FD&C in over 70 years was passed, which is known as the Food Safety Modernization Act (FSMA).

FSMA is a comprehensive top-to-bottom renovation of the US food safety regulatory framework that shifts the focus from responding to foodborne illness to preventing it.[5] FSMA builds upon the principles of HACCP with an approach based on *preventive controls* that include:

- Sanitation
- Supplier Verification
- Food Process
- Allergen Controls
- Recall Plan

Companies are required to perform risk-based activities via supplier controls or a Foreign Supplier Verification Program (FSVP) to verify that food imported into the US is manufactured to the same food safety standards as those required of US producers. Other food products regulated by FDA (e.g., seafood,[6] juice,[7] low-acid canned foods[8]) as well as meat, poultry and certain egg products (regulated by USDA[9]) have been under HACCP requirements for many years.

Many countries have also devoted efforts to modernize their legislative framework for the safety of food commodities. For example, the Canadian Food Inspection Agency (CFIA) has consolidated fourteen sets of existing food regulations into a single set of regulations, which and is called the Safe Food for Canadians Regulations (SFCR).[10]

Australia and New Zealand share a joint food regulatory system known as Food Standards Australia New Zealand (FSANZ),[11] which also endorses the CAC guidelines for HACCP as part of their Food Standards Code[12] to ensure consistency at a national level. Similarly, Directive 852/2004[13] of the European Parliament on the hygiene of foodstuffs mandates that all food business operators implement procedures based on HACCP principles.

Table 1. Examples of regulatory frameworks related to food safety around the world

Country or Region	Legislation	Description
United States	FSMA	Comprehensive US food safety regulatory framework that shifts the focus from responding to foodborne illness to preventing it
Canada	SFCR	Require that certain food businesses prepare, keep, maintain and implement a written HACCP-type preventive control plan (PCP) to demonstrate how hazards and risks to food are addressed
Australia and New Zealand	FSANZ	Endorses the CAC guidelines for HACCP as part of their Food Standards Code[14] to ensure consistency at a national level
European Union	Directive 852/2004	Mandates that all food business operators implement procedures based on HACCP principles

3. Third-Party Auditing

Verification of adherence to and compliance with proper food safety practices is essential for effective food safety management. Besides internal auditing, third-party audits are conducted for several reasons, from compliance with customer requirements to a genuine desire for continuous improvement of food operations.

In 2000, a group of European retailers decided to collaborate on harmonizing their approach to food safety, regardless of where the food originated, was processed and consumed, into what became the Global Food Safety Initiative (GFSI).[15] GFSI does not set standards but rather has published a set of science-based benchmarking requirements[16] that are based on the international standards established by Codex.

Under GFSI, entities known as Certification Program Owners (CPO) develop audit programs to assess alignment with the benchmarking requirements.[17] Compliance by food companies with these requirements leads to certification under any of the programs created by the CPO.[18] CPO accredit certification bodies (CB) who are third-party audit companies that use the criteria under each certification program (CP) to audit the food operations of certification seekers (Figure 1). There are currently multiple certification programs (CP) recognized by GFSI, including:

- BRC (British Research Consortium)
- SQF (Safe Quality Food)
- IFS (International Featured Standards)
- FSSC (Food Safety System Certification) 22000
- GRMS (Global Red Meat Standard)[19]

> Globally, GFSI certifications have become a typical requirement for supplier approval and monitoring of performance, with the same trend expanding to India, China, Southeast Asia and Latin America.

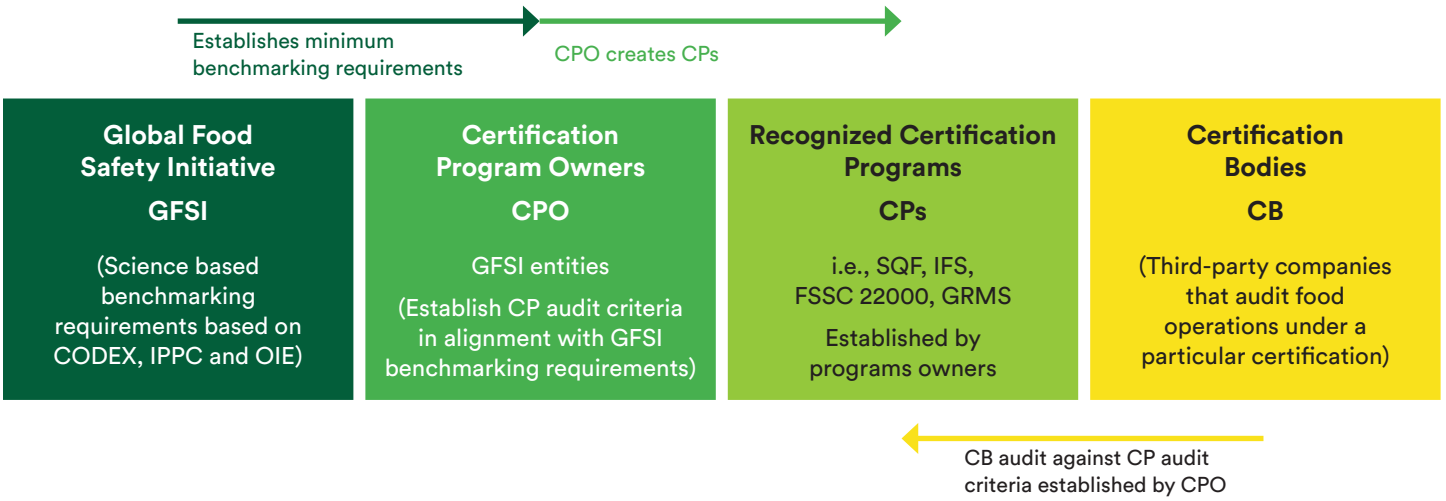


Figure 1.

It is important to note that neither the GFSI benchmarking requirements nor any of the certification programs recognized by GFSI are regulatory in nature. However, GFSI works closely with CPO to drive consistency of the benchmarking requirements with government regulations, thus GFSI-recognized certification can help the industry assure they are meeting government regulations (e.g., FSMA) while enhancing the safety of our food supply.

4. Case Study: Hygiene/Environmental Monitoring for Sanitation Effectiveness Verification

Besides the HACCP requirement for monitoring Critical Control Points (CCP), as part of effective food safety management and as an industry best practice, monitoring of other implemented food safety control measures (e.g., prerequisite programs) is necessary to assess whether they are under control, identify potential trends, produce an accurate record as evidence of implementation and use in future verification procedures.

Sanitation has long been considered a critical part of food plant operations and a cornerstone of Good Manufacturing Practices (GMPs) that is essential in safe food production.

Third-party certification programs have evolved to require validation and verification of the efficacy of sanitation protocols. One example of these programs heading in that direction is FSSC 22000, which states the following as part of their audit criteria (version 4.1)[20]:

11.3 Cleaning and sanitizing programs: *Cleaning and sanitizing programs shall be established and* ***validated*** *by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.*

11.5 Monitoring sanitation effectiveness: *Cleaning and sanitation programs shall be* ***monitored (and verified)*** *at frequencies specified by the organization to ensure their continuing suitability and effectiveness.*

Under FSMA, verification activities are formally required to ensure that preventive controls such as sanitation are consistently implemented and effective in minimizing hazards. As an example, environmental monitoring by collecting and testing environmental samples for a pathogen of concern or appropriate indicator organism is required if the contamination of a ready-to-eat (RTE) food with an environmental pathogen is a hazard the facility identified as requiring a preventive control.[21]

An environmental monitoring program (EMP), while not a control by itself, provides verification of the effectiveness of sanitation practices, particularly if following a "seek and destroy" approach, as well as the performance of other environmental control measures (e.g., zoning, traffic patterns, sanitary design).

Besides facilitating compliance with regulatory requirements and alignment with third-party (e.g., GFSI) audit criteria, implementing robust environmental controls coupled with proactive monitoring can help protect brands and public health, and contribute to business success via continuous improvement.

A robust monitoring program for microbial environmental controls draws on information gathered from visual inspections, microbiological testing and some form of rapid testing to inform decisions related to the sanitary conditions of a facility and manufacturing equipment. **It can also serve to demonstrate to regulators and customers that the company is strongly committed to food safety.**

One approach to rapid testing is to monitor surfaces for food, microbial and organic residue with adenosine triphosphate (ATP), which is a simple assay that provides results in a matter of seconds. It can enable making immediate assessment of the effectiveness of cleaning and taking corrective actions if needed while on the floor. Moreover, it can allow companies to track and analyze data over time, which can reveal patterns and trends in cleaning effectiveness to be addressed before a surface becomes a niche for microbial (e.g., pathogen) harborage with potential to cross-contaminate the food being produced or handled.

Evolving food safety regulations and third-party audit programs around the world frequently require justification of decision-making based on data gathered as part of monitoring of preventive control measures. **ATP testing can offer a complementary and reliable validation and verification method.**

5. What Does the Future Look Like?

With the focus of domestic and international regulations as well as third-party audit programs moving from reaction to prevention and placing accountability on food companies to understand and control their risks, **a risk-based approach to managing food safety is expected to be the predominant model that companies will need to follow.**

Proactive food companies are already leveraging trending and analysis of the data gathered from monitoring efforts to ensure that environmental controls are adequate to meet regulatory expectations, allow them to maintain their third-party certifications and help drive continuous improvement.

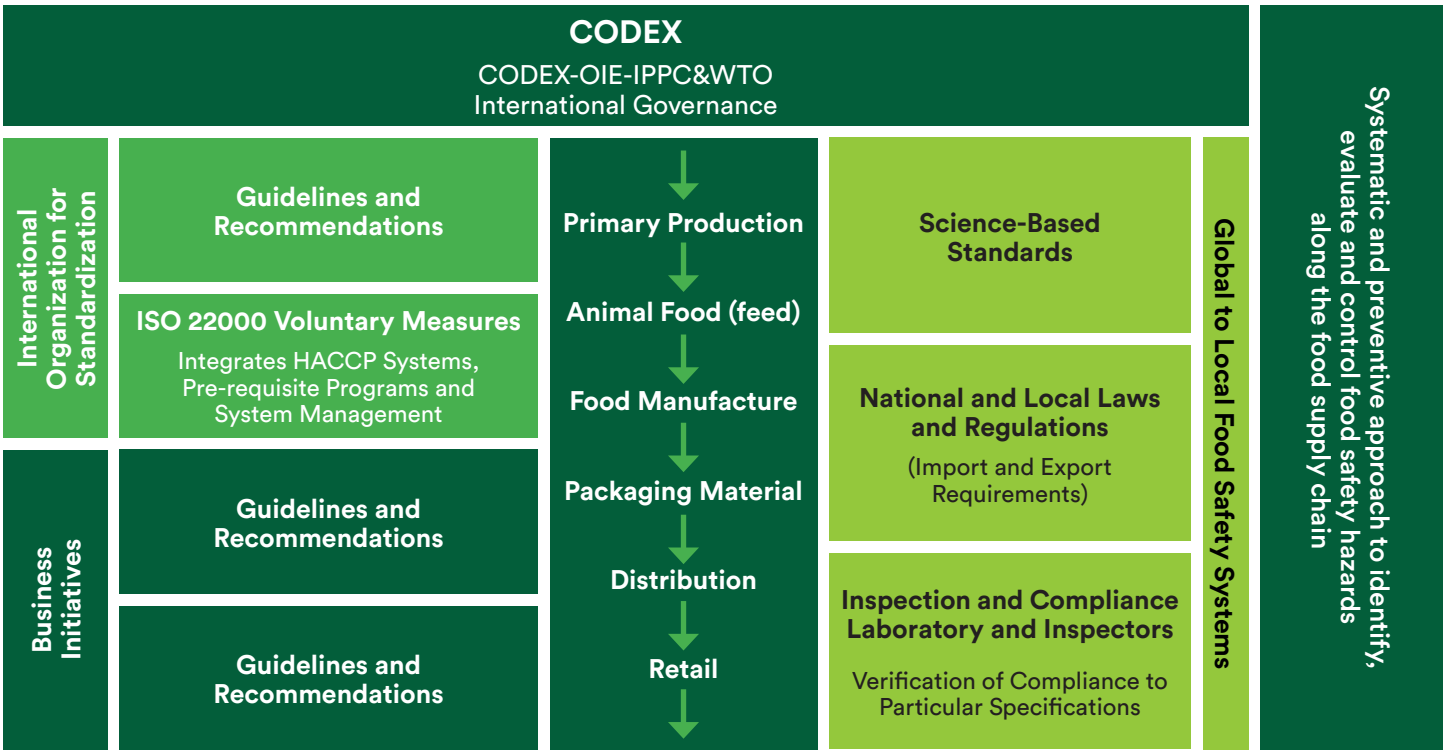
> Even so, because of large-scale or more frequent outbreaks, an increasing use of new technology and additional testing is expected, which may in turn or as a result drive up the number of recalls, which are already common today. Capitalizing on tests results and other monitoring information available and focusing efforts to control areas of greatest risk as indicated by data, can provide the best protection from a regulatory, reputational and operational perspective.

Learn more about hygiene monitoring at **info.neogen.com/Clean-Trace**

Appendix A

Acronym	Definition
ATP	Triphosphate
BRC	British Retail Consortium
CAC	Codex Alimentarius Commission
CB	Certification Bodies
CCP	Critical Control Point
CFIA	Canadian Food Inspection Agency
CP	Certification Programs
CPO	Certification Program Owners
EMP	Environmental Monitoring Program
FDA	Food and Drug Administration
FD&C	Food, Drug and Cosmetic Act
FSANZ	Food Standards Australia New Zealand
FSMA	Food Safety Modernization Act
FSSC	Food Safety System Certification
FSVP	Foreign Supplier Verification Program
GFSI	Global Food Safety Initiative
GMPs	Good Manufacturing Practices
GRMS	Global Red Meat Standard
HACCP	Hazard Analysis and Critical Control Points
IFS	International Featured Standards
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
NASA	National Aeronautics and Space Administration
OIE	World Organization for Animal Health
RTE	Ready-to-Eat
SFCR	Safe Food for Canadians Regulations
SQF	Safe Quality Foods
USDA	United States Department of Agriculture

Relationship Between Global and Local Food Safety Systems



Appendix B

[1] http://www.fao.org/fao-who-codexalimentarius/about-codex/en/

[2] http://www.fao.org/fao-who-codexalimentarius/codex-texts/en/

[3] https://www.iso.org/iso-22000-food-safety-management.html

[4] http://uscode.house.gov/browse/prelim@title21&edition=prelim

[5] https://www.fda.gov/food/guidanceregulation/fsma/

[6] https://www.fda.gov/food/guidanceregulation/ucm2006764.htm

[7] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm

[8] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/default.htm

[9] https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp

[10] http://www.inspection.gc.ca/food/toolkit-for-businesses/handbook-for-food-businesses/eng/1481560206153/1481560532540?chap=0

[11] http://www.foodstandards.gov.au/Pages/default.aspx

[12] http://www.foodstandards.gov.au/code/Pages/default.aspx

[13] https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32004R0852

[14] http://www.foodstandards.gov.au/code/Pages/default.aspx

[15] https://www.mygfsi.com/

[16] https://www.mygfsi.com/certification/benchmarking/benchmarking-overview.html

[17] "Auditing Against Different Regulatory Requirements", Mike Robach, GFSI. Presented at 2018 IAFP Annual Meeting, Salt Lake City, July 9, 2018

[18] https://www.mygfsi.com/certification/certification/how-to-achieve-certification.html

[19] https://www.mygfsi.com/certification/recognised-certification-programmes.html

[20] https://www.fssc.com/schemes/fssc-22000/documents/fssc-22000-version-6/

[21] https://www.govinfo.gov/content/pkg/FR-2015-09-17/pdf/2015-21920.pdf

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