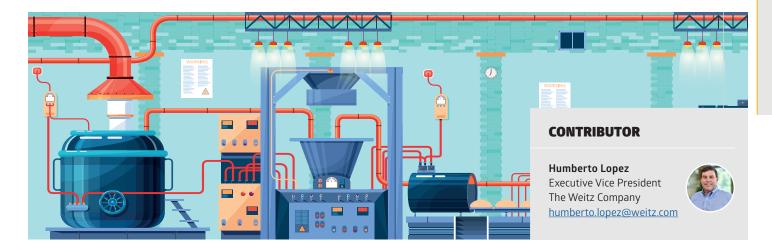


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This resource guide is a summary of regulations and can be used as a starting point to study and understand the implications, compromises and guidelines related to the food supply chain. By no means this should be considered legal advice nor it was prepared by an Attorney.



/ INTRODUCTION

Food safety has always been a major area of focus for processors and distributors of food and beverage products. Major recalls and outbreaks that occurred during the 90's and the 2000's brought another perspective to the impact of not having a cohesive food safety and product recall program.

News about foodborne illness outbreaks caused by poor sanitation and food safety disseminated very rapidly and the public became very aware of the connotations and consequences of food safety issues.

Based on this, food processors and distributors have been developing and implementing their own corporate food safety programs, to not only become a good citizen by protecting the consumers, but also looking to protect their brands and companies.

Even before January 4, 2011, when President Obama signed the bill that brought the Food Safety Modernization Act (FSMA), several worldwide organizations focused on improving and promoting food safety throughout the supply chain, but lacked the ability to enforce the application of well-known food safety initiatives and guidelines. Processors usually teamed up with companies to develop joint programs, promote research and enhance the quality and integrity of the supply chain.

There are numerous organizations worldwide that focus

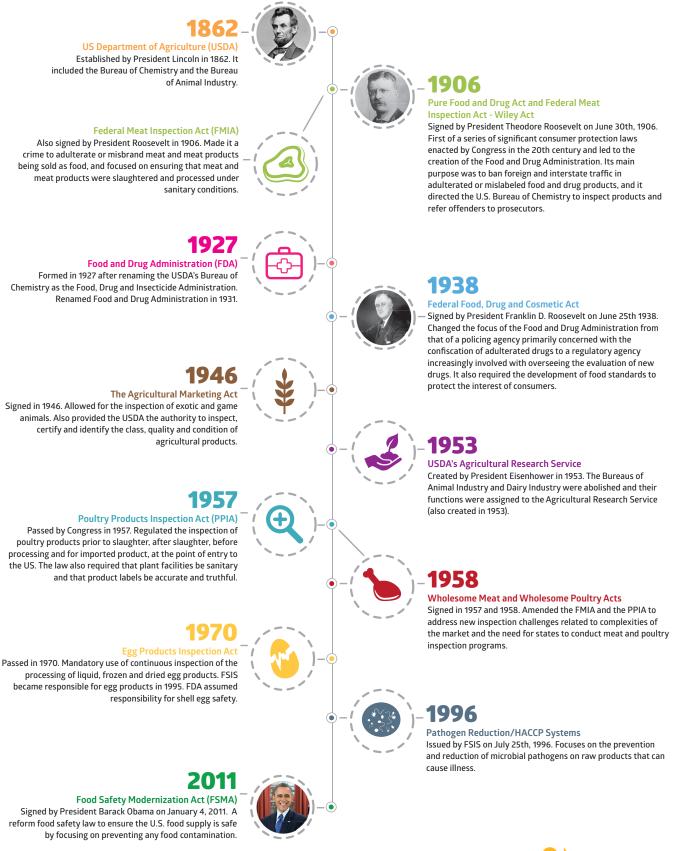
on implementing and enforcing good manufacturing practices applicable to food and beverage and each one targets specifics markets, products, and geographical areas. Some have been developed by countries or multi-national organizations, some by the processors themselves either jointly or as peer groups and some by universities and governments.

As a result, there is a very comprehensive list of regulations, standards and codes that apply to all aspects of the food and beverage supply chain.

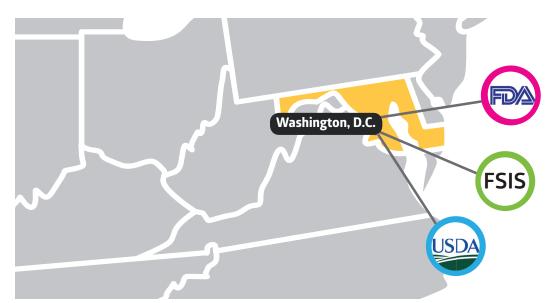
Becoming knowledgeable and complying with regulations is paramount for all processors and distributors. With a lack of compliance and follow up, this will prevent them from reaching their consumers and distributors both domestically and internationally. Furthermore, it can expose them to severe situations that can harm the consumers and affect their business.

This has become not just a matter of complying with codes and regulations but also a matter surviving in a very competitive market with a very sophisticated, informed and demanding consumer base.

/ HISTORY OF FOOD SAFETY REGULATIONS



/ UNITED STATES ORGANIZATIONS



U.S. Corporate Headquarters of Organizations



United States Department of Agriculture (USDA)

The USDA is in charge of managing and regulating the constant changes in food processing and distribution guidelines and regulations throughout the entire supply chain. This includes the inspection of domestic product, imports, and exports; conducting risk assessments of facilities and processes; and educating the public on the importance of food safety.

www.usda.gov



Food and Drug Administration (FDA)

FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods and feed and veterinary products. FDA is empowered by the U.S. Congress to enforce the Federal Food, Drug and Cosmetic Act.

www.fda.gov/



Food Safey Inspection Service (FSIS)

FSIS is the public health agency of the USDA that is responsible for ensuring that the commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. It draws its authority from the Federal Meat Inspection Act of 1906, the Poultry Products Inspection Act of 1957 and the Egg Products Inspection Act of 1970. It focuses on products that contain more than 3% meat or 2% poultry and egg products (liquid, frozen or dried). Shell eggs, meat and poultry that are not under the jurisdiction of the FSIS are regulated by the FDA.

www.fsis.usda.gov



/ FOOD SAFETY MANAGEMENT SYSTEMS

Hazard Analysis Critical Control Point (HACCP)

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

7 PRINCIPLES OF HACCP



Conduct a hazard analysis

Identify food safety hazards and preventive measures the plan can apply to control these hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.



Establish corrective actions

These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters the supply hain.





Identify critical control points

Point, step, or procedure in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.



06

Establish procedures for ensuring the HAACP system is working as intended

Validation ensures that the plants do what they were designed to. Plants are required to validate their own HACCP plans.





Establish critical limits for each critical control point

A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level.





Establish documentation

Establish record-keeping and documentation procedures.





Establish critical control point monitoring requirements

Monitoring activities are necessary to ensure that the process is under control at each critical control point.





International Organization for Standardization (ISO) 22000

The consequences of unsafe food can be serious and ISO's food safety management standards help organizations identify and control food safety hazards. As many of today's food products repeatedly cross national boundaries, international standards are needed to ensure the safety of the global food supply chain. ISO 22000 applies to any organization within the food supply chain.

ISO 22000 MAJOR GOALS



Plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer



Demonstrate compliance with applicable statutory and regulatory food safety requirements



Evaluate, assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction



Effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain



Ensure that the organization conforms to its stated food safety policy



Demonstrate such conformity to relevant interested parties



Seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to ISO 22000:2005





/ FOOD SAFETY CERTIFICATIONS

FOOD SAFETY SYSTEM CERTIFICATION (FSSC-22000)

01

Designed to provide food and beverage companies with an ISO-based food safety management system certification; based on ISO-22000



Recognized by the Global Food Safety Initiative (GFSI)



Effectively manages food safety responsibilities within the food and beverage processors and distributors industries



Defines requirements for integrated processes that work together to control and minimize food safety hazards



Ensure consumer trust in the supply of safe food and beverages



ARE YOU FSSC-22000 OR SQF CERTIFIED?

What do you think about the certification?
What would you add? What do you find out-of-date?

Join the conversation on Twitter.



<u>@TheWeitzCompany</u> | #foodsafetycertification

SAFE QUALITY FOOD CERTIFICATION



Its goal is to deliver consistent, globally recognized food safety and quality certification programs for the food and beverage industry



Based on Hazard Analysis Critical Control Point (HACCP)



Process and product certification standard



Level 1, 2 and 3 certifications



Recognized by retailers and foodservice providers around the world



Recognized by the Global Food Safety Initiative (GFSI)



Spans throughout the food and beverage supply chain (manufacturing, distribution and agent/broker) industries



Administered by the Food Marketing Institute (FMI)



Demonstrates suppliers commitment to produce safe, quality food, and comply with applicable food legislation







/ FOOD SAFETY MODERNIZATION ACT (FSMA)

The Food Safety Modernization Act was signed on January 4, 2011 by President Obama and was easily the biggest change since 1983.

This act applies to all facilities registered under the Bioterrorism Act of 2002 and is based on HACCP. Its focus is on prevention instead of correction. As a result, the FDA can order a product recall at anytime. Companies can be assessed a fee for any required reinspection or product recall.

The FDA will institute new regulations every two years based on a review of foodborne threats. The Act has expanded access to food company records for tracking purposes or if there is a suspected health risk. Therefore, records need to be kept up to date. Food manufacturers and processers can expect the FDA to publish new allergen management guidelines.

The FDA has the ability to suspend production at a food facility for a suspected public health risk. This is why food companies MUST report hazardous practices with a corrective action plan. Keep in mind, high risk facilities must be inspected every three years and low risk companies every seven years. The regulations contain a "watch dog "clause to protect employees that report unsafe conditions. In addition, small manufacturers and processors that make up to \$500,000 in sales may be exempted.

www.fda.gov/



FOOD FOR THOUGHT...

"If it's not in a file, it doesn't exist or never happened"



DID YOU KNOW...

The Food Safety Modernization Act is based on the Hazard Analysis Critical Control Point (HACCP) management system.



/ FOOD SAFETY ASSOCIATIONS BY INDUSTRY

Animal Protein



POULTRY

- U.S. Poultry and Egg Association
- American Poultry Association
- Turkey Federation



BFFF

- Cattlemen's Beef Board
- U.S. Meat Export Federation
- American Meat Institute
- Danish Meat Institute



PORK

- National Pork Producers
- U.S. Pork Center of Excellence

Bakeries



- American Society of Baking
- American Institute of Baking

Dairy



- International Dairy Foods Association
- U.S. Dairy Export Council
- Dairy Farmers of America
- National Yogurt Association

Snacks



Snack Food Association

Coffee



National Coffee Association of USA

Others



- National Pasta Association
- National Association of Flavors and Foods
- Master Brewers Association of the Americas
- International Bottled Water Association
- Pet Food Institute
- National Grain and Feed Association







American Institute of Baking (AIB)

The AIB is committed to protecting the safety of the global food supply chain and delivering high value educational and technical programs. They provide food safety inspections, audits, certifications, food safety education, research and technical services.

Comprehensive Good Manufacturing Practice (GMP) Inspections evaluate the adequacy of:

- Operational methods and personnel practices
- Maintenance for food safety
- Cleaning practices
- Integrated pest management
- Adequacy of prerequisite and food safety programs

AIB also provides training in HACCP and accreditation, and testing for allergens, microbiological, and airborne.

www.aibonline.org/aibOnline/en/



Pasteurized Milk Ordinance (P.M.O)

- Ranges from animal health, handling, distribution and storage
- Outlines standards for Grade A Milk (fluid/fresh) production and processing
- Latest version updated in 2009 (revision in 2007)
- Recommended for legal adoption by states
- Varies by state
- Establishes minimum standards for design of the production and distribution facilities
- + Raw, ultra pasteurized temperature (UHT), and aseptic

www.fda.gov/downloads/Food/





10 AMERICAN MEAT INSTITUTE SANITARY DESIGN PRINCIPLES

- O1 Surfaces cleanable to a microbiological level
- Accessibility for inspection, maintenance, cleaning and sanitation
- Made of compatible materials
- No product or liquid collections
- 05 Hollow areas hermetically sealed
- Sanitary operational performance
- 07 Validated cleaning and sanitizing protocols
- 08 No niches
- Hygienic compatibility with other plant systems
- 10 Hygienic design of maintenance enclosures

www.meatinstitute.org/







Grain and Feed



Grain and Feed FSMA Applies To:

- Grain Elevators
- Feed, Feed Ingredients and Pet Food Manufacturers
- Grain Processors (Corn, Flour, Soybean, Wheat, etc.)
- Biofuel Producers Manufacturing Distiller Dried Grains
- Exporters of Grain, Feed, Feed Ingredients and Process
 Commodities

Grain and Feed FSMA Requirements

- Hazard Analysis to develop written analysis of biological, chemical and physical hazards
- Establish preventive controls
- Written food safety plan to comply with the HACCP plan and facilitate inspections
- Determine and control high risk products with vulnerability study
- Update HACCP plans periodically
- Flexibility for raw commodities storage, allergens or sanitation standards
- Implementation July 2012 phased approach
- Renew registrations under Bioterrorism Act every two years

Implications of Grain and Feed FSMA

- Increased Product Safety Contract Demands
 - Suppliers
 - Farmers largely exempt
- More Focus on Suppliers such as audits, sampling, and third-party certification
- Implications for transporters and conveyance
- Enforcement in foreign countries and trade considerations



/ GLOBAL ORGANIZATIONS





Global Food Safety Initiative (GFSI)

The GFSI is a private organization established and managed by the Consumer Goods Forum. It was issued under Belgian law in May of 2000.

It maintains and generates guidelines to benchmark food safety standards for manufacturers as well as farm assurance standards. It is a worldwide business driven initiative for the continuous improvement of food safety management systems to ensure confidence in the delivery of safe food to consumers.

The objectives of GFSI are:

- Reduce food safety risks by delivering equivalence and convergence between effective food safety management systems
- Manage cost in the global food system by eliminating redundancy and improving operational efficiency
- Develop competencies and capacity building in food safety to create consistent and effective global food systems
- Provide a unique international stakeholder platform for collaboration, knowledge exchange and networking

www.mygfsi.com/



5 WORLD HEALTH PRINCIPLES

- Prevent food contamination with pathogens spreading from people, pets and pests
- Separate raw and cook foods to prevent contamination of the cook foods
- Cook foods for the appropriate length of time and at the appropriate temperature to kill pathogens
- O4 Store food at the proper temperature
- Use safe water and raw materials

www.who.int/en/





European Food Safety Authority (EFSA)

- + Established in 2002
- Provides independent scientific advice and communication on existing and emerging risks associated with the food chain
- Covers all matters with a direct or indirect impact on food and feed safety, including animal health and welfare, plant protection and plant health, and nutrition

www.efsa.europa.eu/



PAC SECURE - PAC 220 - CANADA

- Canadian organization established in 1950
- Provide leadership for the packaging industry
- Applies HACCP principles to packaging
- Sponsored by Kraft, Natrel, Nestlé-Canada, Parmalat-Canada, Smucker Foods of Canada Co., Sobeys Inc., and more than 80 other packaging companies

http://www.pac.ca/pacsecure.html



BRITISH RETAIL CONSORTIUM (BRC)

- Vision is to work with its members to create a vibrant and sustainable retail industry for the future
- Represents the interests of the retailers
- Actively involved with producers across the supply chain
- Made a significant contribution to the development of Food 2030 Initiative UK

Major Goals:

- Campaign to promote and defend retailers' interests
- Advise retailers of threats and opportunities to their business
- Improve the perceptions of retailing in the UK
- Offer members a range of services and products which add value to their business

http://brc.org.uk/



GOALS OF THE FOOD 2030 INITIATIVE UK...

- Consumers are informed, can choose and afford healthy, sustainable food. This demand is met by profitable, competitive, highly skilled and resilient farming, fishing and food businesses, supported by first class research and development.
- Food is produced, processed, and distributed, to feed a growing global population in ways which:
 - Use global natural resources sustainably
 - Enable the continuing provision of the benefits and services a healthy natural environment provides
 - Promote high standards of animal health and welfare
 - Protect food safety
 - Make a significant contribution to rural communities
 - Allow us to show global leadership on food sustainability
- Our food security is ensured through strong UK agriculture and food sectors and international trade links with European Union and global partners, which support developing economies.
- The UK has a low carbon food system which is efficient with resources – any waste is reused, recycled or used for energy generation.









China Food and Drug Administration (CFDA)

10 CFDA PRINCIPLES

- To organize relevant authorities to draft laws and regulations on the safety management of food, health food and cosmetics
- To exercise comprehensive supervision on the safety management of food, health food and cosmetics in accordance with laws; organize and coordinate supervision work on the safety of food, health food and cosmetics carried out by relevant authorities.
- To organize and carry out investigation and impose punishment on serious safety accidents of food, health food and cosmetics
- Registration, draw up, revise and promulgate national standard of drugs
- To draft and revise good practices for drug research, manufacturing, distribution and use, and supervise their implementation

http://eng.sfda.gov.cn/WS03/CL0755/



To control the quality of drugs and medical devices in manufacturers, distributors and medical institutions

07

To regulate radioactive pharmaceuticals, narcotics, toxics, psychotropics, and other controlled drugs and devices in accordance with law

08

To draw up and improve qualification system for licensed pharmacist, supervise and direct the registration of licensed pharmacist

09

To direct national drug regulations and comprehensive supervision on the safety management of food, health food and cosmetics.

10

To carry out exchanges and cooperation in drug regulations, relevant safety management of food, health food and cosmetics with foreign governments and international organizations



