Understanding FSMA: HACCP, HARPC and the Preventive Controls for Human Food Rule

The evolution of the original Hazard Analysis Critical Control Point (HACCP) principles towards Hazard Analysis Critical Control Point (HACCP) is discussed and requirements within the Food Safety Modernization Act (FSMA) regulation are summarized.

Introduction

In 2011, the U.S. Congress passed, and the president signed into law, the Food Safety Modernization Act (FSMA). A key regulation issued under the law is "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food". Among the requirements of the regulation is for food manufacturers to develop Hazard Analysis Risk-Based Preventive Control (HARPC) food safety plans. The underlying approach behind HARPC is close to that taken from globally accepted Hazard Analysis Critical Control Point (HACCP) principles. Both rely on experience and scientific data to proactively identify and evaluate process-specific food safety hazards and to develop appropriate, effective, and verifiable control measures. In this article, the evolution of the original HACCP principles towards HARPC is discussed and requirements within the FSMA regulation are summarized.

Background

Continuing efforts to prevent food from becoming contaminated during growing, processing, and distribution remains a high priority throughout the world. The World Health Organization (WHO) estimated that, in 2010, 600 million illnesses and 420,000 deaths occurred from consumption of contaminated food 19. In the United States, the Centers for Disease Control and Prevention (CDC) estimates that approximately 48 million foodborne illnesses occur each year 4. Many of these only cause minor symptoms that quickly pass. However, severe cases result in approximately 128,000 hospitalizations and 3000 deaths per year.

CDC surveillance data collected from U.S. State Departments of Health, hospital records, and death certificates show that less than half of reported illnesses are traced to known human microbial pathogens, such as norovirus, *Salmonella* spp., *Campylobacter* spp., *Clostridium perfringens*, pathogenic strains of *E. coli*, and *Listeria monocytogenes* 19,22. More often, the microorganisms responsible for illness remains unknown 23. Most cases of foodborne illness are related to food handling and preparation practices in restaurants and home kitchens 1,4. However, highly publicized multistate outbreaks have been linked to contamination that occurred on farms, in packing houses, and in processing plants that distributed products over great distances.

Several factors have been identified to contribute to this trend 20. Consumer preference has shifted away from thermally processed food products (e.g. canned or blanched/frozen) toward novel, minimally-processed, fresh tasting products such as cut fruits and vegetables, salad mixes, ready-to-eat deli products, and un-pasteurized beverages, which have sensory attributes similar to their fresh counterparts. Consumers may therefore be exposed to an elevated risk of illness from such products until new technologies for making them safe are developed. Manufacturers have expanded their global supply chain for foods and food ingredients to an extent where it can be difficult to assure that best practices for safe growing, packing, and processing of foods are followed. Advances in food microbiology and public health have led to discoveries of previously unknown threats to human health, such as highly virulent strains of bacteria and naturally occurring allergenic compounds that can cause severe illness or even death. At the same time, the number of individuals whose immune systems are impaired during recovery from medical treatments has increased.

Foodborne illness also has significant economic costs. In a survey of U.S. food companies that issued a food recall between 2006 and 2011, 77% reported financial losses of at least $30 million, with 23% stating that costs were even higher 17. In 2015, it was estimated that medical costs, legal settlements, income, and productivity losses from plant closures accounted for an annual economic burden of over $15.5 billion 18. It is, therefore, not unexpected that the increasing number of food related recalls, illnesses, and outbreaks have caused wholesale buyers to demand proof of compliance with new food safety standards and government regulators to issue food laws and regulations that raise the standards for safe food production and processing practices.

The Risk-Based Approach to Food Safety and the HACCP Concept

Great strides were taken in the twentieth century to assure the safety of the U.S. food system. A series of federal food safety laws culminated with the passage of the Federal Food, Drug, and Cosmetics Act (FD&C) in 1938 [P.L. 75-717]. Among the provisions of the Act, the U.S. Food and Drug Administration (FDA) was given the authority to investigate illnesses or outbreaks attributed to manufactured foods and to inspect food processing facilities and warehouses for compliance with federal food safety standards. Periodic visits by government sanitarians and end-point product testing were thereafter relied upon for assurances of the safety of food products. If someone became ill from eating a food product or if contamination was found during an inspection, the usual practice was for the government to request that the food company destroy or recall the product. However, over time it became clear to many that the existing resources available for on-site inspections were not adequate to oversee a growing and continually changing food industry. A new approach was needed that placed more responsibility on manufacturers to identify potential food safety hazards for their unique products and processes, develop ways to prevent them from occurring before they become a problem, and to document that all practices and policies are consistently implemented.

The Hazard Analysis Critical Control Point (HACCP) food safety management system has emerged as a better alternative to the inspect and test approach and is now the globally accepted system for assuring buyers, the public, and regulators that they have taken all possible measures to reduce or eliminate potential food safety hazards in their operations. HACCP is a systematic and proactive way to consider risks at each step of a manufacturing process and then develop control measures to prevent or reduce food safety risks to acceptable levels.

Risk-based, preventive approaches to food safety began in the 1960s when the National Aeronautics and Space Administration (NASA) adapted “zero defect” engineering and quality assurance systems for assuring the safety of food taken into outer space. These included applications of “Modes of Failure” concepts that require a thorough understanding of the product and the process in order to predict when a food safety “hazard” can occur. In 1985, the National Academy of Sciences (NAS) recommended that HACCP be incorporated into U.S. food regulations. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) then developed uniform procedures for developing food safety plans known as the seven HACCP principles 21.

Worldwide consensus on the utility of HACCP for maintaining the safety of the global food supply was achieved in 2003 when the World Health Organization’s (WHO) Codex Alimentarius Committee on Food Hygiene issued Hazard Analysis Critical Control Point guidelines for international trade 5. Soon after, the European Union (EU), Canada, Australia, and Japan issued regulations requiring food businesses within their jurisdiction to develop and implement food safety plans based on the NACMCF and Codex HACCP frameworks 3.

Over the last three decades, U.S. government agencies have issued a succession of regulations that required HACCP plan development for certain types of foods. In 1995, all U.S. seafood processing facilities were mandated by the Food and Drug Administration (FDA) to develop HACCP plans 6. Soon after, the United States Department of Agriculture (USDA) required meat and poultry establishments to write HACCP plans 7. In 2001, after a series of food borne illness outbreaks attributed to unpasteurized juice products, FDA directed wholesale juice and cider processors to implement HACCP plans in their operations 8.

In the U.S., full adoption of the HACCP approach for assuring the safety of food came in 2011 when Congress passed, and the president signed into law, the Food Safety Modernization Act (FSMA) [P.L. 111-353]. The law is said to be the most sweeping reform of the U.S. food regulatory system since the 1938 FD&C Act was enacted. FSMA adopts the risk-based, preventive approach of HACCP and expands upon it to address potential hazards that have emerged with the development of modern food production and processing practices. The law grants new authority to the U.S. Food and Drug Administration (FDA) to establish and enforce food safety standards encompassing the entire U.S. food system, including farms that grow, harvest, pack, and hold fresh produce; facilities that process, manufacturer, pack, or hold human or animal food; and shippers and receivers involved in transporting human and animal food. The seven regulations issued under FSMA and a brief description of the scope of each are shown in **Table 1**. Complete information on each regulation can be accessed on the FDA’s FSMA website. The FSMA regulation that has the greatest impact on the food processing and manufacturing industry is “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” 9, often abbreviated to simply the “Preventive Controls Rule”.

Table 1. Definitions of terms used in HACCP 21 and HARPC in the FDA Preventive Controls Rule 2,16

Collection and evaluation of scientific and technical information to determine whether the food safety plan can effectively control significant hazards.

Term	Definition	HACCP	HARPC
Control	(a) To manage the conditions of an operation to maintain compliance with 1) a critical limit in a HACCP plan or 2) a parameter or value in a HARPC plan or (b) The state in which correct procedures are being followed and criteria are being met.	†	†
Control measure	Any action or activity that can be used to prevent, eliminate, or reduce a hazard.	†	
Control point (CP)	Any step at which biological, chemical, or physical factors can be controlled	†	
Correction	An action taken to correct a minor and isolated deviation from an allergen, sanitation, or supply chain preventive control when the problem is not likely to result in distribution of non-compliant food entering the marketplace.		†
Corrective action	Procedures followed when control is lost at a CCP and a process deviation occurs.	†	†
Critical control point (CCP)	A step at which process control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.	†	†
Critical limit	A maximum and/or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control (the terms parameter or value are used more broadly in HARPC).	†	†
Reasonably foreseeable hazards	Those hazards that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would identify for a specific product and process (analogous to potential hazards in HACCP).		†

Reasonably foreseeable hazards requiring a preventive control	Hazards, identified in the hazard analysis, that are of sufficient severity and likelihood of occurrence that one or more preventive controls are needed to significantly minimize or prevent the food from becoming contaminated or produced under conditions that could cause contamination. Analogous to significant hazards in a HACCP plan.		†
Deviation	Failure to meet a 1) critical limit in a HACCP plan or a 2) parameter or value in a HARPC plan resulting in loss of control	†	†
Good Manufacturing Practices for Human Food (GMP)	The FDA regulation (21CFR Part 117 Subpart B) that describes conditions and practices that must be followed for processing safe food under sanitary conditions and which provides the foundation for a 1) HACCP and 2) HARPC food safety plans	†	†
Food Safety Plan	A set of written documents based on risk-based food safety principles.		†
Food Safety System	The outcome of implementing the food safety plan and its supporting elements		†
HACCP	Hazards Analysis Critical Control Point. A risk-based systematic approach to the identification, evaluation, and control of food safety hazards	†	
HARPC	Hazards Analysis Risk-Based Preventive Controls. The risk-based systematic approach for writing a food safety plan that complies with the FSMA preventive controls rule (21CFR 117)		†
HACCP plan	A written document based on the principles of HACCP and that contains the procedures necessary to control significant hazards.	†	

HARPC plan	A written food safety plan based on the principles of HARPC that contains the procedures necessary for compliance with the Preventive Controls for Human Food rule (analogous to HACCP plan).		†
Facility	A domestic or foreign food establishment that is required to register with FDA in accordance with the requirements of 21 CFR part 1, subpart H, “Registration of Food Facilities”.		†
Hazard	A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.	†	†
Hazard Analysis	The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are 1) significant and must be controlled in the HACCP plan or 2) known or reasonably foreseeable and for which a preventive control must be established in the HARPC plan.	†	†
Hazard requiring a preventive control	A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would establish one or more preventive controls to significantly minimize or prevent hazards from occurring.		†
Monitoring	The act of conducting a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.	†	†

Parameters and values	A maximum and/or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a reasonably foreseeable hazard requiring a process, sanitation, allergen, or supply chain control (an expanded definition of critical limit).		†
Prerequisite programs	Facility-wide policies and procedures that provide the basic environmental and operating conditions necessary to produce safe foods.	†	†
Preventive controls	Risk-based reasonably appropriate procedures, practices, and processes to minimize or prevent hazards identified in the hazard analysis as significant.		†
Preventive Controls qualified individual (PCQI)	An individual who has successfully been trained in the development and application of risk-based preventive controls or who is otherwise qualified through job experience.	†	†
Risk	The threat of any particular hazard to cause harm to consumers based on its severity of outcome and probability of occurrence.	†	†
Significant hazard	A potential food safety hazard that, because it can cause severe illness or injury and is sufficiently likely to occur warrants control in the HACCP plan (analogous to a reasonably foreseeable hazard requiring a preventive control in HARPC).	†	
Validation	Collection and evaluation of scientific and technical information to determine whether the food safety plan can effectively control significant hazards.	†	†

Verification	Activities other than monitoring that determine the validity of the food safety plan and that the system is operating according to the plan.	†	†

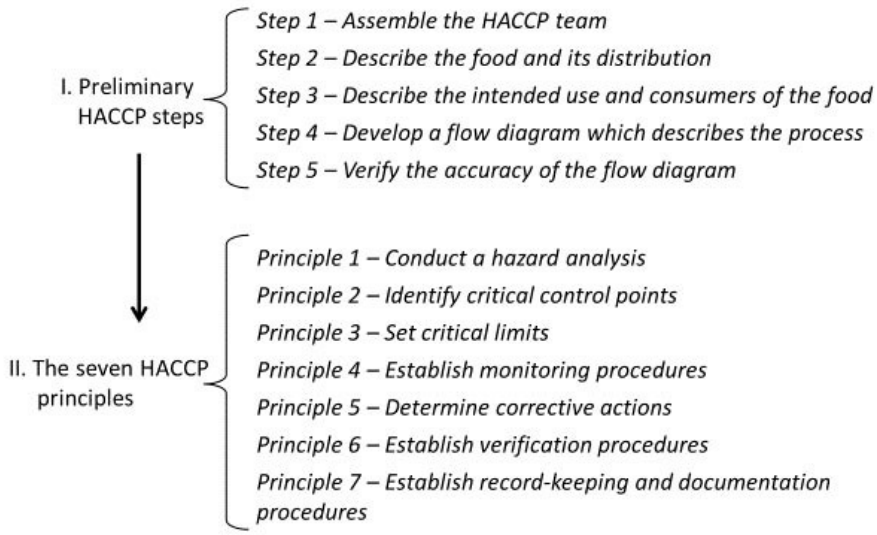
Writing a HACCP Food Safety Plan

Because the foundation of the Preventive Controls Rule is based on the risk-based HACCP approach for maintaining a safe food supply, it will be helpful to understand the NACMCF system for writing a HACCP plan 2. HACCP terms, their definitions, and a summary of the process of writing a HACCP plan are summarized in **Table 2** and **Figure 1**, respectively. The task of writing a HACCP plan must first begin with preliminary steps that assure the plan accurately reflects the specific process, product, and environmental conditions within the processing facility. The five preliminary steps are described as follows.

Table 2. Examples of food safety prerequisite programs

- Allergen management
- Buildings and grounds maintenance
- Chemical control
- Cleaning and sanitizing
- Consumer complaint tracking
- Employee hygiene
- Employee training
- Environmental testing
- Equipment preventive maintenance
- Food defense/security
- Foreign material control
- Glass control
- Heating/ventilation/air conditioning (HVAC)
- Labeling
- Maintenance of handwashing and toilet facilities
- Pest control
- Product tracing and recall
- Raw materials and supplier specifications
- Receiving, storage, and distribution
- Transportation
- Waste disposal
- Water and ice safety

Figure 1. Steps toward developing a Hazard Analysis Critical Control Point (HACCP) food safety 21



Step 1: Assemble the HACCP Team

The HACCP team is responsible for writing the HACCP plan and is accountable for maintaining it. A HACCP coordinator is selected to help lead and support the team. The team should be drawn from individuals that have experience and expertise in the company's products and processes. The ideal team is composed of representatives from quality assurance, sanitation, and plant operations with at least one member from upper management since investment in new facilities and equipment may be necessary. Individuals with expert knowledge and training in food microbiology and process engineering are obvious assets in the risk assessment process. If needed, outside resources such as consultants, trade or professional associations, or university extension specialists may be brought in to join the team. Each person on the team should have an appropriate level of training on the fundamentals of HACCP.

Step 2: Describe the Food and Its Distribution

Microbiological food safety risks are dependent on the inherent physical and chemical characteristics of the ingredients and the finished product. These are used later in the plan writing process for documenting handling, storage, and processing specifications. Names of ingredients in the product, any processing aids, potential food allergens, water sources, packaging materials, or potentially toxic chemicals used during manufacturing are recorded. The expected shelf life of the product and any temperature requirements during shipping (e.g. refrigerated, frozen, ambient) should also be recorded.

Step 3: Describe the Intended Use and Consumers of the Food

The expected use of the product by the consumer is important when assessing risks. For instance, is the product intended to be eaten without any further preparation or cooking (ready-to eat product)? Are there specific directions for preparation of the food? Will the intended consumers be the general public? Or, will the food be marketed to specific groups that are especially susceptible to foodborne illness such as infants, the elderly, those with weak immune system, or those taking immune suppressing medications?

Step 4: Develop a Flow Diagram that Describes the Process

Because a HACCP plan is process oriented, a clear description of each step under the control of the establishment is needed. Important process steps might include receiving and storage of ingredients, washing, mixing, grinding, chopping, heating, packaging, and shipping of the final product.

Step 5: Verify the Accuracy of the Flow Diagram

A process flow diagram written in a meeting room may not be accurate or up-to-date. The HACCP team should check the accuracy and comprehensiveness of the diagram by going into the plant and confirming that it accurately reflects the flow of food and ingredients as they are transformed into the finished product. On-site verification of each process step will help the team understand time and location relationships between steps that will be useful later in the hazard identification process. After the review is completed, any deficiencies should be corrected before proceeding to the seven HACCP principles.

Once the preliminary steps are completed, the HACCP team can begin to write the plan according to the seven HACCP principles (**Figure 1**). The seven principles are a sequence of activities used to systematically identify and establish control measures and

monitoring procedures for the most significant hazards, what to do if control measures fail, that the plan is based on the most up-to-date scientific knowledge, and that it is consistently followed as intended. The seven principles are described as follows.

Principle 1: Conduct a Hazard Analysis

A food safety hazard is any substance, object, or property that may cause a food to become unsafe for human consumption in the absence of its control. Potential hazards are typically categorized as:

1. Biological hazards, e.g. disease-causing bacteria, viruses, parasites, and molds,
2. Chemical hazards, e.g. naturally present food toxins above FDA tolerance levels or chemicals that can be poisonous if used improperly, such as cleaners, sanitizers, lubricants and fuels, or substances in food that can cause dangerous allergic responses in sensitive populations.
3. Physical hazards, e.g. bone fragments, metal pieces, glass shards, stones, and jewelry that could cause injury or choking if ingested.

A hazard analysis is the process of collecting and evaluating information on potential hazards that may be introduced, controlled, or enhanced at each step in the manufacturing process. Each step where a hazard must be controlled is termed a control point (CP). Because time, energy, and resources are always limited, the HACCP team must select a list of fewer hazards that pose the greatest risk to consumers and thus warrant control in the HACCP plan. These are classified as “significant hazards” because they can cause severe illness to consumers if uncontrolled and their likelihood of occurrence is relatively high. Severity is a function of the potential magnitude and duration of illness or injury (e.g., how long an individual may be sick, and whether hospitalization, death or long-term complications are likely outcomes).

The likelihood of occurrence is estimated by considering past associations of the food product and processing method with outbreaks of foodborne illness or recalls, the method of preparation and processing, conditions during transportation, expected storage conditions, and whether the product requires further preparation or cooking steps on the part of the consumers before serving the food. This information should be gathered in the preliminary steps.

Lower risk (not “significant”) hazards can then be managed outside of the HACCP plan through less stringently controlled facility-wide procedures and policies, known as prerequisite programs. These provide the basic environmental and operating conditions necessary to produce safe foods and are often not unique to any particular process or product. Prerequisite program standards are largely drawn from the FDA mandated Good Manufacturing Practices (GMP) 9 and any other food safety regulatory or customer specific requirements. Procedures for implementing prerequisite programs are generally documented as standard operating procedures. The types of prerequisite programs used by food manufactures are numerous and varied depending on the needs of the facility. Examples of typical prerequisite programs are shown in **Table 3.**

Principle 2: Identify Critical Control Points (CCP)

For each significant hazard, a control measure must be implemented that will prevent, eliminate, or reduce the risk to an acceptable level. The control step takes place at one or more steps in the process known as Critical Control Points (CCP). In HACCP, CCPs are typically process control steps, which can include inspection test results upon receipt of raw materials, pasteurization or commercial sterilization, cooking, chilling, acidification, addition of chemical preservatives, metal detection, and labeling.

Principle 3: Set Critical Limits (CL)

For each control measure established as a CCP, critical limits (CL) must be set to distinguish between a safe and an unsafe process. These are ideally minimum or maximum numerical values that are easily monitored, such as heating temperature and time, cooler temperature, pH, water activity (aw), physical dimensions, product flow rate or residence time in a heating system, and ingredient weights. However, conformity or deviation from acceptable testing standards, presence or absence of metal, and correct labeling are also examples of critical limits.

Principle 4: Establish Monitoring Procedures

Monitoring is the planned sequence of observations or measurements to assess and accurately document whether or not a CCP is under control. Monitoring activities include a visual observation, an automatic readout from a temperature or flow rate recording instrument, or a check that test results fall within an allowable range. If monitoring shows that the requirements of the CL are met, the hazard is said to be “in control”. If there is a deviation from the CL, the CCP is “out of control” and immediate action must be taken to correct the situation.

Principle 5: Determine Corrective Actions (CA)

When monitoring shows that a CCP is not under control, corrective actions (CA) must be in place to assure that non-compliant product does not enter the marketplace. By determining CAs well before a crisis happens, confusion on what to do when a deviation from a CL occurs can be avoided. Corrective actions include immediately isolating the non-compliant product for a subsequent determination of its safety and making an immediate process correction to assure no further products are affected. Once

the CCP is back under control, a determination can be made on what to do with the affected product. Options include disposing of the product, re-processing it, or safely diverting it to animal feed. If there is a complete system failure and the product left the facility, the company can issue a product recall. Later, an investigation must be conducted to determine the root cause of deviation and how to prevent it from happening again.

Principle 6: Establish Verification Procedures

Verification is defined as those activities, other than monitoring, that determine if the HACCP plan is operating as intended and the control measures are scientifically valid for producing a safe product. Verification activities may include regular reviews of monitoring activities and corrective actions to assure that the procedures established in the plan have been diligently followed. An annual review of the entire HACCP plan, most importantly the process flow chart and the hazard analysis, is essential to determine if there have been any changes to process steps, processing conditions, and product lines since the last review and that the scientific basis for the effectiveness of each control measure remains valid.

Principle 7: Establish Record-Keeping and Documentation Procedures

Records are written evidence that all aspects of the HACCP plan are continually followed. It is important to fully document how the HACCP team conducted its risk assessment in the hazard analysis, what basis it used to determine significant hazards and to keep an historical record of monitoring, corrective actions, and verification activities. For many food processors, intense record keeping is thought of as an onerous exercise. However, government inspectors and third-party auditors rely on records as verification that food products are consistently produced under the safest possible conditions. If, another company recalls a product that is similar to yours, thorough documentation of all aspects of your food safety system could provide critical evidence that you are not at fault for introducing adulterated products into commerce.

Table 3. Food safety regulations issued under the U.S. Food Safety Modernization Act (FSMA).

Regulation	Scope
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food 9	Animal food facilities must have a food safety plan in place that includes an analysis of hazards that need to be controlled and risk-based preventive controls to minimize or prevent those hazards from occurring.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals 10	Food facilities must have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards from occurring.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals 11	Importers of food into the U.S. must perform certain risk-based activities to verify that that food has been produced in a manner that meets applicable U.S. safety standards.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption 12	Growers, harvesters, packers, and those who hold fruits and vegetables likely to be eaten raw must comply with science-based minimum farm food standards.
Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications 13	Establishes a voluntary program for the accreditation of third-party certification bodies, known as third-party auditors, to conduct food safety audits and issue certifications of foreign entities and the foods for humans and animals they produce.
Sanitary Transportation of Human and Animal Food 14	Shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food must use sanitary practices that ensure the safety of that food.
Mitigation Strategies to Protect Food Against Intentional Adulteration 15	Food facilities must develop risk reduction strategies to prevent intentional adulteration from acts intended to cause wide-scale harm to public health.

FSMA and the Preventive Controls for Human Food Rule

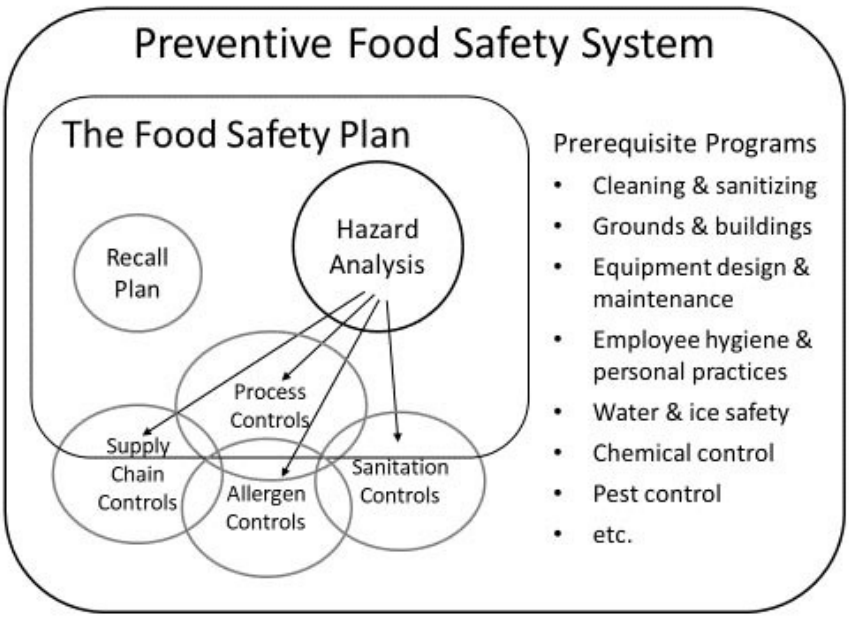
The requirements within the Preventive Controls Rule apply to commercial food operations that manufacture, process, pack, or hold human food for consumption in the United States that are already required to register with FDA under section 415 of the FD&C Act. The rule is equally applied to businesses in other countries that export food to the U.S. Foods imported from other parts of the world must now be in compliance with the requirements of each of the FSMA regulations including requirements for importers to perform certain risk evaluation activities to verify that food brought into commerce within the U.S. meets applicable U.S. food safety standards.

Entities defined by FDA as retail food establishments, restaurants, and home-based businesses are not subject to the Preventive Controls Rule requirements because they are not required to register. USDA inspected meat and poultry processors and home-based processors are specifically excluded from FSMA and therefore not subject to the Preventive Controls Rule. Seafood, low acid canned foods, and 100% juice products are not covered under FSMA because they are already covered under other federal food safety regulations. Although farms are not required to register, processing activities conducted on farms (mixed type facilities) are subject to the Preventive Controls Rule. Certain exemptions to parts of the rule are discussed later.

The framework of the Preventive Controls Rule has been established to provide the food industry with the tools they need to comply with the regulation, but most importantly, to reduce the incidence of outbreaks and recalls. The HARPC approach retains most of the elements within HACCP including developing and implementing a food safety plan that includes a hazard analysis, monitoring procedures, corrective actions, verification methods, and record keeping procedures. Compliance with Good Manufacturing Practices (GMP) managed through prerequisite programs also remains an important foundation for the food safety plan.

However, there are some differences in terminology (**Table 2**) and plan development stages (**Figure 2**). FDA has introduced the term “food safety system” to mean all measures taken by the manufacturer to keep food safe. The food safety system is made up of two elements. The first is the “food safety plan”, known also as the HARPC plan. It is reserved for managing higher risk foreseeable hazards and is analogous to managing “significant hazards” in a HACCP plan. The HARPC plan includes a hazard analysis, preventive controls and associated monitoring and corrective actions, and a recall plan. The second element of the food safety system consists of the already mentioned prerequisite programs that are used to control lower risk hazards and provide a supporting foundation for the HARPC plan (**Table 3**). Within the HARPC hazard analysis, plan writers are provided with two options for how foreseeable food safety hazards should be addressed: (i) the hazards can be controlled within the HARPC plan through implementation of stringent preventive controls or (ii) the hazards can be controlled within prerequisite programs where the monitoring, corrections, and verification requirements are more flexible. The process begins with a set of preliminary steps as follows.

Figure 2. The hazard analysis risk-based preventive controls food safety system 16.



1. Preliminary Steps

Preliminary steps are the same as those developed for a HACCP plan. A food safety team is assembled, and the product, its distribution, and the intended use, and the end user of the product are identified. A process flow diagram must also be developed and verified. However, the Preventive Controls Rule requires that at least one member of the food safety team be a "preventive controls qualified individual" or PCQI. A PCQI is an individual who has successfully completed training in the development and application of risk-based preventive controls that is at least equivalent to that received under a standardized curriculum recognized by FDA. An individual can also attain PCQI status as proficient in developing and applying a food safety system by other means, such as through job experience. The PCQI is responsible for oversight of the food safety plan including determining that preventive controls are effective, conducting onsite audits of suppliers, reviewing records to assure that monitoring and corrective actions are complete, that corrective actions taken are appropriate, and that the plan is re-evaluated at least every year.

2. Hazard Analysis, Preventive Controls, Monitoring, and Corrective Actions

The hazard analysis remains at the core of the food safety plan. Under the Preventive Controls Rule, the term "reasonably foreseeable hazards", is introduced to mean all biological, chemical, and physical hazards occurring naturally or that are introduced unintentionally or for purposes of economic gain. These are analogous to the list of potential hazards identified at the beginning of the HACCP hazard analysis. FDA has characterized foreseeable hazards as those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would identify. From this definition, FDA makes it clear that education and training are important qualifications for members of the food safety team that will be conducting the hazard analysis.

The number of "reasonably foreseeable hazards" identified must then be pared down to those that "require a preventive control" to significantly minimize or prevent the food from becoming contaminated or produced under conditions that could cause contamination. This is analogous to the procedure for identifying higher risk "significant hazards" controlled in a HACCP plan. The remaining lower risk foreseeable hazards must still be controlled within the food safety system through one or more prerequisite programs. FDA has established four types of preventive controls, each requiring monitoring, corrective action, verification, and record keeping procedures.

- **Process preventive controls** are procedures, practices, and processes to control reasonably foreseeable hazards occurring at specific process steps identified in the flow diagram. They are equivalent to process controls established as critical control points in a HACCP plan. Specific "parameters and values" must be set to indicate when the hazard is under control. Monitoring activities must be established to notify when a loss of control occurs and corrective action procedures must be carried out when a process preventive control has failed. Those who already have a HACCP plan, can easily merge already established CCPs, monitoring procedures, critical limits, and corrective actions into a HARPC food safety plan.
- **Sanitation preventive controls** are practices and policies that include cleaning and sanitizing food-contact surfaces, preventing microbial and chemical cross-contamination, and monitoring for environmental pathogens. In HACCP, risks related to inadequate sanitation practices were typically controlled in prerequisite programs and many can still be controlled that way in a Preventive Controls Rule food safety system. However, given an increasing number of outbreaks and recalls traced to post-processing contamination of ready-to-eat foods, it is no surprise that the Preventive Controls Rule now requires manufacturers to consider preventing sanitation deficiencies in the more stringent HARPC plan. When deficiencies related to cleanliness and cross contamination can easily be corrected in a timely manner, the full requirements of corrective actions proscribed for a HACCP plan (e.g. isolation of the affected product and evaluation of its safety) are not required. Instead, the FDA allows the manufacturer flexibility to make an immediate "correction" to a minor and isolated problem. For instance, re-cleaning a food preparation surface showing signs of residual food debris. However, more prescriptive corrective actions may be necessary if unsanitary conditions exist for an extended period of time or that pose an immediate and significant risk to consumers.
- **Allergen preventive controls** are procedures, practices, and processes to assure that the presence of food allergens in ingredients and final products are labeled correctly and that cross-contamination during processing cannot occur. Compliance with the Food Allergen Labeling and Consumer Protection Act (FALCPA) (P.L. 108-282) is required to prevent unintentional illness on the part of sensitive individuals from exposure to allergens in milk, eggs, peanuts, tree nuts, fish, shellfish, soy, and wheat. Monitoring actions can include regular checks for mislabeled ingredients and finished products, or post-cleaning visual checks and allergen test kit results that could indicate a serious cross contamination risk. Corrective actions must be taken whenever monitoring indicates that measures taken to prevent exposure of the public to a food allergen are inadequate. Depending on the results of the hazard analysis, some allergen hazards can also be controlled through sanitation and supply chain preventive controls, or within prerequisite programs.
- **Supply chain preventive controls** are actions or procedures to minimize or reduce a hazard in raw materials or ingredients. These actions must be applied by the supplier and are monitored by the food manufacturer. Supply chain controls include inspecting for the presence of a certificate of analysis (COA) with each shipment, site visits by the manufacturer for assuring conformance with food safety standards, or results from third party audits. A supply chain prerequisite program can rise to preventive control status within the HARPC plan if no other preventive controls are adequate to control the foreseeable hazard.

3. Verification and Validation Procedures

The Preventive Controls Rule states that, for each preventive control, verification activities must be conducted to take into account the nature of the preventive control and its role in the facility's food safety system. Verification is required to assure that the food safety plan is consistently implemented including reviewing monitoring and corrective action records within seven working days after the they are created, that appropriate decisions about corrective actions are being made, and that process monitoring instruments are regularly calibrated.

A reanalysis of the entire food safety plan must take place at least every 3 years or whenever (1) significant changes in food products and processing methods within the facility could result in new foreseeable hazards or significantly increase the risk level of a previously identified hazard, (2) the manufacturer becomes aware of new information on potential hazards, or (3) part or all of the HARPC plan is known to be ineffective. Process preventive controls must be validated through scientific studies or other means to assure they are adequate to control the foreseeable hazards identified in the hazard analysis. Validation of sanitation, allergen, and supply chain preventive controls are not required in the HARPC plan although scientifically valid environmental and product testing procedures must be used for all verification activities.

4. Record Keeping Procedures

An integral part of the preventive control system is keeping good records. Written records benefit the manufacturer by providing evidence to buyers and regulators that that the HARPC plan is consistently followed as planned. The following records must be kept in order to comply with the Preventive Controls Rule:

- the hazard analysis,
- preventive controls for each identified hazard and verification that they effectively control the hazards,
- monitoring records to ensure preventive controls are consistently performed,
- a full account of any corrective actions taken,
- the supplier approval and verification program,
- the recall plan,
- all testing and auditing results, and
- the results of the food safety plan reanalysis

All the required records must be retained at the facility for at least 2 years after the date they were prepared.

5. Recall Plan

A recall is an action taken by a food establishment to remove a product from distribution. Despite all efforts to prevent food safety hazards from occurring, there is always the possibility that an unsafe product has left the control of the manufacturer and entered the marketplace. A recall plan is not intended to prevent food safety problems but can limit exposure of the public to harm and perhaps limit liability to the manufacturer. Under the Preventive Controls Rule, a written recall plan is mandatory in a HARPC plan if a preventive control was established. If a company discovers a problem that has a reasonable probability of causing serious injury, illness, or death to consumers, an immediate recall is required. If FDA finds that a company is not responding quickly enough to a situation that requires a recall, it may issue a mandatory recall notification and, if necessary, shut down the facility. FDA requires that recall plans include all steps necessary to conduct the recall including assigning responsibility for taking those steps. Required procedures include:

- notifying customers about the food being recalled, including how to return or dispose of the affected product,
- notifying the public at large when appropriate to protect public health such as through a pre-prepared press release approved by FDA,
- conducting regular checks to verify that the recall is being effectively carried out, and
- determining appropriate disposition of the returned or recovered recalled product such as reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

Exemptions to the Preventive Controls Rule and Modified Requirements

Although all FDA regulated food businesses that manufacture, process, pack, or hold human food for consumption are covered under the Preventive Controls Rule, certain exemptions are available where only some aspects of the rule apply.

A "qualified facility" exemption is available to facilities having (1) less than $1,000,000 in annual total food sales plus inventory (adjusted for inflation since 2011) or (2) less than $500,000 (inflation adjusted) in 3-year average annual sales provided that the

average monetary value of all food sold directly to qualified end users is greater than that sold to other purchasers. A qualified end-user means (1) the consumer of the food, or (2) a restaurant or retail food establishment located in the same state or Indian reservation or no more than 275 miles from the qualified facility and is purchasing the food for direct sale to consumers. Qualified exempt facilities must comply with Current Good Manufacturing Practices (cGMP) 9 but are not required to write a complete a HARPC plan nor are they required to meet the full record keeping provisions of the rule. However, exemptions are not automatic. The manufacturer must submit a form to FDA every 2 years that attests that their 3-year average annual sales figures and/or sales distribution values determined from tax documents, invoices, or other accounting documents meet the exemption requirements. They must also have conducted a hazard analysis that justifies their conclusion that they already have adequate preventive controls in place. If part of their claim involves compliance with state or local food safety regulations, they must also present evidence to that effect. It needs to be mentioned that FDA can withdraw a qualified exemption if they find that foodborne illnesses were directly linked to the facility or is otherwise necessary to protect the public health.

FDA also exempts certain low-risk products and processing activities conducted on farms (mixed type facilities) that have fewer than 500 full time employees or 3-year average annual food sales plus inventory of less than $1,000,000 (inflation adjusted). Lower-risk products and processes that take place on a mixed type facility include baked goods, candy, jams, jellies, maple syrup, vinegar, and other processed foods that do not require time/temperature controls for safety. The complete list can be found in the body of the preventive controls for human food rule 9.

Food manufacturers who are eligible for exemptions to the rule need to keep in mind that wholesale distributors and buyers are under no obligation to accept FSMA exempt food and may require full compliance with the regulation as a condition of purchase.

Conclusions and Future Directions

The risk-based, proactive control approach used for HACCP food safety plan development is globally accepted as the most effective way for food manufacturers to prevent recalls, outbreaks, and associated financial losses. The Preventive Controls Rule has adopted many of the established HACCP principles while adding new terminologies and procedures for food safety plan development. Compliance dates for the Preventive Controls Rule have passed and food manufacturers in the U.S., and those importing food to the U.S., can expect increased scrutiny from FDA for assurances that all aspects of the regulation are followed.

Writing a HARPC food safety plan can be challenging, especially for those with no prior experience with HACCP. The materials presented in this chapter are only a cursory review of HACCP and HARPC. Readers are encouraged to seek out courses offered by university extension, commodity groups, or consulting businesses on risk-based food safety plan development. A high-quality course will generally take 2–3 days and will include active discussions and breakout work groups that provide the hands-on experience necessary to write a food safety plan. Risk-based preventive controls food safety plans are living documents that must be regularly updated over time to keep up with rapid changes in demand for new products, advances in food technology, and our understanding of potential biological, chemical, and physical hazards in the food supply chain.

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FSMA and Food Safety Resources

Food Safety Modernization Act (FSMA) Resources from Penn State. Articles, fact sheets, videos, FAQs, upcoming trainings, and tools for understanding each of the FSMA regulations.

Food Safety and Quality short courses and workshops from the Penn State Department of Food Science and Penn State Extension.

Food Safety Modernization Act (FSMA) resources from the U.S Food and Drug Administration (FDA)

Trainers

Lead trainers at Penn State trained and certified by the Food Safety Preventive Controls Alliance (FSPCA)

- Martin Bucknavage MS, MBA Senior Food Safety Extension Associate
- Kerry Kaylegian Ph.D. Associate Research Professor
- Richard Andrew Kralj, M Ed., RDN, LDN Food Safety and Nutrition Extension Educator
- Luke LaBorde, Ph.D. Professor of Food Science

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