

Food Safety Modernization Act (FSMA) Readiness Checklist

Under FSMA law, growers, producers, harvesters, processors, and shippers for US foods need to fully comply under the Hazard Analysis and Risk-Based Preventive Controls (or HARPC) program. A complement to HACCP (Hazard Analysis and Critical Control Points), HARPC expands its reach to manage and prevent food risks during the entire process to reduce foodborne illness.

To comply with HACCP and HARPC, food manufacturers must implement a food safety plan. Use the following checklists to guide the development and implementation of your food safety plan.



HACCP (Hazard Analysis and Critical Control Point)

A system which identifies, evaluates, and controls hazards that are significant for food safety. HACCP focuses on identifying hazards and applying critical control points (CCPs) to prevent contamination.

HARPC (Hazard Analysis and Risk-Based Preventive Controls)

An evolution of HACCP methodology. HARPC adopts the risk-based approach of HACCP and expands upon it to address potential hazards that have emerged with the development of modern food production and processing practices. HARPC introduces mandatory science-

based preventive controls across a food processor's entire supply chain to significantly minimize or prevent hazards.

HACCP and HARPC

Both focus on assuring food safety but differ on execution. A HARPC plan isn't considered a replacement of HACCP, but as a necessary upgrade to its conventional plan standards based on prevention. Both have 7 principles in which the execution of a food safety plan is built upon.

HACCP	HARPC
Principle 1 <input type="checkbox"/> Conduct a hazard analysis—identify any hazards and appropriate control measures.	<input type="checkbox"/> Conduct a hazard analysis—identify hazards due to the specific foods or food ingredients in the food or due to the various processing, manufacturing, packing, and holding steps applied to the foods
Principle 2 <input type="checkbox"/> Determine critical controls points (CCPs)—the timing in which controls are applied. Essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.	<input type="checkbox"/> Institute Preventive Controls—develop and implement a series of risk-based controls to significantly minimize or prevent the identified hazards to ensure the safety of the food it manufactures, processes, holds and distributes.
Principle 3 <input type="checkbox"/> Establish critical limits—the maximum and/or minimum value to which a biological, chemical or physical hazard must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.	<input type="checkbox"/> Monitor effectiveness of the controls—establish and implement a written monitoring program, which ensures the firm is conducting regular evaluations of the facility's control measures to determine that the preventive controls are working
Principle 4 <input type="checkbox"/> Establish monitoring procedures—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.	<input type="checkbox"/> Establish and implement written corrective action measures to be deployed if preventive controls are not effectively implemented or if there are discrepancies in the safety plan.
Principle 5 <input type="checkbox"/> Establish corrective actions—steps taken to prevent foods which may be hazardous from reaching consumers.	<input type="checkbox"/> Establish verification measures—design and implement verification steps to ensure that the HARPC plans are operating correctly to prevent or minimize food safety and adulteration hazards.
Principle 6 <input type="checkbox"/> Establish verification procedures—activities, other than monitoring, that determines the validity of the plan and that the system is operating according to the plan	<input type="checkbox"/> Establish a supply-chain program—identify and use only approved suppliers, conduct supplier verification activities, review supplier's controls
Principle 7 <input type="checkbox"/> Establish record-keeping and documentation procedures—records that include specific details	<input type="checkbox"/> Establish record-keeping and documentation procedures—the FDA requires that a written record be kept of the entire plan including testing & monitoring, corrective actions, supply-chain, and training

CREATING A FOOD SAFETY PLAN

A Food Safety Plan (FSP) consists of the primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury. There are twelve steps to help ensure the successful implementation and integration of a food safety plan consisting of preliminary steps to be completed before the HACCP and HARPC principles are applied (after Step 5).

- STEP 1:** Assemble a HACCP team with the appropriate product-specific knowledge and expertise to develop an effective Food Safety Plan.
- STEP 2:** Describe the product in full detail (general description of the food, ingredients, processing methods and distribution).
- STEP 3:** Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, immunocompromised individuals, the elderly, etc.).
- STEP 4:** Diagram a clear, simple outline of all steps in the process which are under the direct control of the manufacturer.
- STEP 5:** Verify the flow diagram to confirm that it is aligned with actual operations and verify the accuracy and completeness of the flow diagram.
- STEP 6:** Identify and evaluate hazards associated with food being produced/processed, including the severity and likelihood of each potential hazard occurring. Determine which must be addressed in the plan.
- STEP 7:** Determine Critical Control Points (CCPs)—those areas where previously identified hazards may be eliminated. Determine at what steps in the process controls can be applied to prevent or eliminate the hazards that have been identified. For each critical control point, identify the preventive measures to prevent the hazard.
- STEP 8:** Establish critical limits and develop processes that limit risk at CCPs. Define the criteria that must be met to control the hazard at that point. Critical limits must be established by regulatory standards and guidelines.
- STEP 9:** Monitor CCPs and develop processes for ensuring that critical limits are followed. Monitoring procedures must be able to detect loss of control at the CCP and should provide this information in time to make appropriate adjustments so that control of the process is regained before critical limits are exceeded.
- STEP 10:** Establish actions to be taken if a critical limit is not met and assign responsibility. Evaluate and correct the cause of non-compliance, making process adjustments where necessary.
- STEP 11:** Establish procedures for verification to determine whether the HACCP system is working correctly. Determine the records needed to show that the critical limits have been met, and the system is in control.
- STEP 12:** Establish proper documentation and recordkeeping for all HACCP processes to ensure that the business can verify that controls are in place and are being properly maintained.

HAZARD ANALYSIS

Hazard analysis is the process of collecting and interpreting information on hazards and conditions leading to their presence to determine which are significant for food safety and should be addressed in your food safety plan.

Hazard Analysis consists of two steps:

HAZARD IDENTIFICATION

- Identify potential hazards associated with a food or process. With HARPC, this includes “known or reasonably foreseeable hazards.”
- Develop a list of potential biological, chemical, or physical hazards which may be introduced, increased, or controlled at each step in the production process. To be HARPC compliant, the hazards to be addressed go beyond the conventional biological, chemical, and physical risks for actual and potential food safety hazards. This includes radiological hazards and economically motivated adulteration.

HAZARD EVALUATION

- Evaluate the severity and likelihood of each potential hazard to decide which ones must be addressed in the HACCP or Food Safety Plan.
- List any hazards associated with each step in the production of the food along with any measures that are used to control the hazards.
- Create a written assessment of the hazards identified.

PREVENTIVE CONTROLS

The preventive controls requirements apply to anyone that manufactures, processes, packs, or holds human food for consumption in the United States, whether the facility is domestic or foreign.

Preventive controls are designed to be implemented prior to a threat event to reduce and/or avoid the likelihood and potential impact of a successful threat event.

- Define Process Controls - the procedures, practices, and processes to control parameters during operations. Examples of process controls are cooking and refrigeration, and product formulation.
- Establish Food Allergen Controls to prevent or mitigate allergen cross-contact within a facility and to ensure all food allergens are correctly labeled.
- Put in place Sanitation Controls to assure the facility is maintained in a sanitary manner to control hazards such as environmental pathogens. Environmental monitoring is required if contamination of a Ready-to-Eat food with an environmental pathogen such as *Listeria monocytogenes* is a hazard requiring a preventive control. Examples include sanitation procedures at food surface contact points, sanitation of utensils and equipment and staff hygiene training.
- Develop and communicate Supply Chain Controls. These are preventive controls for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.
- Ensure a Recall Plan is established and in place. This written plan must include procedures that describe the steps to be taken and assign responsibility for taking those steps should a product recall occur.
- Follow Current Good Manufacturing Processes (cGMP). These regulations are provided by the FDA to guide the design, monitoring, and maintenance of manufacturing facilities.

INTENTIONAL ADULTERATION

Intentional Adulteration is a deliberate attack on the food supply by a person or group of people external or internal to a food business with the intent to cause wide-scale harm to public health through the food supply. Preparing for and preventing intentional adulterations requires facilities to implement a written Food Defense Plan. Plan requirements include:

- Conduct a Vulnerability Assessment to identify weaknesses or points of exposure in the process steps for each type of food manufactured or held at the facility.
- Identify and implement mitigation strategies at each actionable process step to provide assurances that vulnerabilities will be minimized or prevented.
- Develop monitoring, corrective action, and verification procedures to ensure mitigation strategies are performing as expected and actions are in place should they fail.
- Ensure that both personnel assigned to the vulnerable areas and supervisors take food defense awareness training and training on mitigation strategies.
- Ensure that records are kept and maintained for food defense monitoring, corrective actions, and verification activities.

SANITARY TRANSPORTATION

The Sanitary Transportation of Human and Animal Food rule requires those involved in transporting human and animal food by motor or rail vehicle to follow recognized best practices for sanitary transportation. The goal of the rule is to prevent practices during transportation that create food safety risks, and addresses equipment, operations, and personnel at all stages of transportation. Preventive controls to reduce these risks include:

EQUIPMENT

- Ensure all trailers and transportation units are washed out either prior to or upon return to distribution locations.
- Inspect all trailers before the trip begins at the facility where the food is loaded for general sanitary conditions.
- Verify that all trailers are at the required temperature and capable of maintaining the required temperature, including pre-cooled, prior to loading of refrigerated/frozen loads.
- Monitor to ensure appropriate sanitation and condition of transportation vehicles is maintained during loading, transporting, and unloading of food products, including cleaning and sanitizing processes and pest control.
- Use appropriate packaging/packing equipment for food products and transportation units.
- Ensure loading and unloading equipment is cleaned and sanitized.

OPERATIONS

- Set and manage appropriate temperature control procedures during transport and staging of food products.
- Verify that loading procedures prevent cross-contamination when transporting mixed product loads of allergen and non-allergen containing foods and Ready-to-Eat and raw foods.
- Maintain records for all information related to operations and food safety, including procedures, training and transportation documentation, and establish a record retention policy.

PERSONNEL

- Enforce employee hygiene practices to prevent cross-contact and contamination of transported food product.
- Ensure drivers and personnel at all stages of receiving, unloading, storage, loading and delivery are trained on sanitary transportation practices.
- Establish good communication procedures between the shipper, transporter, and receiver of food products.

CROSS-CONTAMINATION

Cross-contamination in food occurs when allergens, chemicals, toxins, or physical contaminants are unintentionally transferred from one food to another. Key requirements to prevent cross-contamination are addressed in Current Good Manufacturing Processes (cGMPs) and preventive controls designed in the Food Safety Plan. These include:

- Design your production flow to keep employees who work with raw food out of areas where Ready-to-Eat foods are processed.
- Separate production processes for raw food from processes for cooked foods.
- Establish process controls to maintain proper food temperatures in staging, cooking, and storage processes.
- Design air circulation so that clean filtered air flowing from finished product and packaging areas flow towards raw product areas, not the other way around.
- Ensure the proper storage and separation of foods containing allergens from allergen-free foods.
- Store Ready-to-Eat foods and the tools and utensils used with them separate from Raw foods.
- Adopt practices to prevent the occurrence of cross-contamination from chemical contaminants through the use of food safe cleaning products and lubricants and proper storage of non-food safe chemical products.
- Use color-coded cleaning utensils to support zone separation and reduce the risk of cross-contact and contamination of food products.
- Ensure robust cleaning and sanitation processes are used when cleaning all food contact surfaces and equipment.
- Train employees on Good Manufacturing Processes and cross-contamination situational awareness.
- Implement GMPs to address employee hygiene, hand washing, and the use of Personal Protective Equipment to prevent cross-contact and contamination of food products.
- Control visitor access and conduct visitor training to ensure plant visitors are aware of the potential they have of cross-contact with and contamination of food products.

ENVIRONMENTAL MONITORING

Environmental Monitoring is a process used in facilities that produce food that assesses how effectively the plant is being cleaned and involves swabbing various surfaces for pathogens and sending those samples out to a lab for analysis.

You may need an Environmental Monitoring Program if any of the following describes your process or product:

- Does your process have a kill step or possible exposure to contamination/cross-contamination?
- Do you have product exposed to the environment after a kill step, after final production (e.g., food grade paper) and before packaging or food contact material packaging (e.g., sandwich wraps, bakery boxes and food film packages)?
- Are your products a collection of Ready-to-Eat products combined to produce a Ready-to-Eat food that doesn't include a kill step (Ex. lunch meat and soft cheeses)?
- Is your product refrigerated and conducive to the growth of Listeria (Ex. deli meat, raw cheese/milk, seafood and sprouts)?

If you've qualified for an Environmental Monitoring program from the questions above, then the below components of the program need to be completed.

- Perform a risk assessment to identify the specific pathogens that may exist in the environment.
- Ensure that monitoring procedures are written and have been scientifically validated and performed at a defined frequency.
- Identify the test organism (pathogen or indicator) for each specific monitoring area.
- Identify the proper locations and number of test sampling sites and frequency to determine whether preventive controls are effective.
- Determine a testing laboratory to process and analyze test samples. If not in house, ensure the external/third party lab is accredited.
- Identify Corrective Action Procedures should testing reveal the presence of pathogens.
- Establish a verification program to evaluate the process for risks to sampling sites.
- Establish a documentation process to track monitoring procedure and methods, training records, pre-operation inspection logs, corrective action records, and hold/release records.

FOOD SAFETY CULTURE

Food Safety Culture can be defined as the food safety attitudes, values and beliefs shared by a group of people, typically within a company, organization or industry. It is the product of employee habits, attitudes, beliefs, and behaviors that determine the commitment to and robustness of an organization's food safety management.

Components of a robust Food Safety Culture should include:

- Ensure Food Safety Culture is driven by senior management to demonstrate a strong commitment and mindset around food safety for other employees to follow.
- Ensure all employee training on Food Safety is monitored and up to date with records kept and completed for every employee.
- Provide the proper equipment and tools to safely process foods, including correct utensils, sanitation equipment and systems across all zones, easy and regular monitoring at every workstation, and metal detection equipment.
- Require employees to take readings of calibrated, food control points at specific times and make proper recordkeeping part of their regular routine.
- Establish a company Food Safety Policy that can be accepted by all employees with measurable annual and long-term objectives to meet the vision and policy.
- Ensure there is a process to link the Company's Food Safety Policy to the organizations individual sites, with objectives defined at each level (Company, Site, Key Departments, Operational Departments, Supplier, Contractor).
- Ensure all food contact and materials are inspected and documented upon receipt.
- Establish a process to stay aware of food safety in the industry to respond to internal food contamination or market issues and recalls ensuring you are not buying or using potentially unsafe foods.
- Establish protocols for regular scheduled self-inspections to eliminate careless mistakes.
- Ensure all allergen control protocols are being followed in food production and food service settings.

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