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THE BEGINNER'S GUIDE TO HACCP

Contents

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WHAT IS HACCP?

Hazard Analysis Critical Control Points (HACCP) is an internationally recognized method of identifying and managing food safety related risk and, when central to an active food safety program, can provide your customers, the public, and regulatory agencies assurance that a food safety program is well managed.

Technically speaking, HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards. This analysis goes from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. Because of the structure of this system, HACCP acts as the foundation for every food safety program.

Today, many of the world's best manufacturers and vendors use the system as a basis for their food safety management programs and for compliance with GFSI audit schemes. You may be trying to sell to a big retailers such as Target or Walmart, who requires GFSI certification. The first step in receiving certification is creating a HACCP plan. Simply put, if you are interested in manufacturing food on a large scale, HACCP is mandatory.

A food safety program, however, does not just stop with HACCP. To be effective, prerequisite programs such as pest control, traceability, recall, hygiene, and sanitation need to be developed and implemented. Additionally, it is important to ensure that suppliers and distributors have up to date food safety programs in place with ingredient specifications and a vendor assurance system. The supplies you use affect your end product. For this reason, their food safety program is just as important as yours.

Not sure how to create a HACCP Plan?

Through analysis of hazards and where they can occur, Safe Food Alliance helps implement systems and procedures to minimize risk. Safe Food Alliance will help you create the food safety plan that is right for you that can effectively manage your critical control points.

WHY IS A HACCP PROGRAM IMPORTANT?

Proper implementation of a HACCP program helps reduce:

- The likelihood of customer complaints
- Harm to the public
- Recalls by identifying and controlling potential hazards

With a HACCP plan, the entire staff becomes part owner of your company's food safety culture. With ownership comes greater employee awareness and ultimately continual improvement of a company's products and processes.

Although a HACCP plan does not meet all of the requirements, it meets the majority of the requirements and is the best platform from which to build a FSMA-compliant management system.

HISTORY OF HACCP

Shortly after NASA was established in 1958, the prospect of manned spaceflight raised an important concern: how could they be sure the food astronauts would be eating was safe? If food poisoning is bad on terra firma, the possibility of such an infection in a Gemini capsule could prove fatal. The process had to change. When food safety practices first began, food safety in industrial production relied heavily on product testing. Samples would be extracted from the processed foods and tested for contamination. While useful in many ways, it was not possible to have a high level of certainty that the entirety of a batch of food was safe to eat just by testing a portion of it. In fact, such a huge portion of each batch needed to be tested that very little final product would be left over for consumption.

As a result, NASA partnered with the US Army Laboratories and Pillsbury to develop a more reliable approach to food safety. This new approach focused on preventing the introduction of hazards in the process of manufacturing food, rather than looking for the effects of those hazards in the finished product.

It was decided that NASA's engineering management requirements, Critical Control Points, would be used as a guideline for this food safety initiative. Originally, Critical Control Points (CCP) were used to test weapon and engineering system reliability. By using CCP, NASA and Pillsbury were able to hire contractors to identify and eliminate the "critical failure areas" in the food processing procedures.

The system created by NASA, Pillsbury, and the US Army Laboratories represented a major improvement in safe food production, and by the 1990s, would come to be the internationally recognized HACCP approach to food safety. HACCP is now included in the Codex Alimentarius that is recognized by both the World Health Organization and World Trade Organization for the merit of its guidance on food safety.

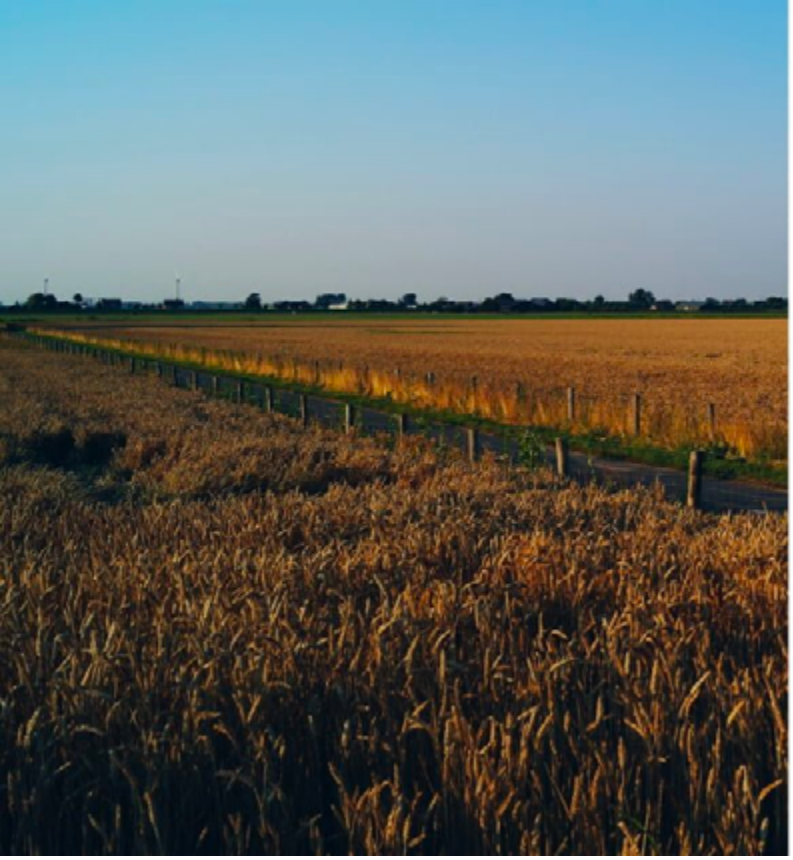
The History of HACCP

HACCP IN ACTION

After the success of NASA program, Pillsbury had a recall on Farina, a cereal used in infant food. Pieces of glass were being found in the food, which caused contamination. A microbiologist at Pillsbury, Howard Baumann, who also helped in the NASA initiative, advocated for the company to adopt a HACCP plan. Because of this outbreak and Baumann's success with HACCP, a panel discussion was held in 1971 at the National Conference on Food Protection. The panel examined Critical Control Points and Good Manufacturing Practices (GMP) in producing safe food. The outcome of this meeting lead to the FDA asking Pillsbury to establish and manage a training program for the inspection of canned foods for FDA inspectors. The program was first held in September 1972 for 21 days, with 11 days of classroom lecture and 10 days of canning plant evaluations. The name of this class was titled, "Food Safety through the Hazard Analysis and Critical Control Point System", and was the first time HACCP was used to educate other food facilities in the industry.

Today, training for developing and implementing HACCP Food Safety management systems are offered by several food safety companies. Safe Food Alliance is an accredited HACCP trainer through the International HACCP Alliance and is qualified to perform nationally recognized HACCP training according to Codex Alimentarius. Secondly, we currently have the resources to conduct HACCP verification audits on your time-table.

"HACCP is important because it prioritizes and controls potential hazards in food production. By controlling major food risks, such as microbiological, chemical and physical contaminants, the industry can better assure consumers that its products are as safe as good science and technology allows. By reducing foodborne hazards, public health protection is strengthened" (International HACCP Alliance). HACCP is a program that both government agencies and food facilities alike have relied on for years and will be a program that continues to have an impact on food safety and in the food industry for years to come.



HACCP VS HARPC

The Food Safety Modernization Act (FSMA) was signed into law by the United States Congress in 2011, with implementation assigned to The Food and Drug Administration (FDA). The essence of FSMA proposed rules is prevention; i.e., a shift from a reactive to a protective and preventative approach. With the globalization of the food supply chain and emerging new food safety risks, it is no longer "what will you do if" but instead becoming "what will you do when" to proactively minimize and/or prevent potential for contamination of food, and also minimize food recalls across our food supply chain.

Under FSMA, the FDA now has a legislative mandate to require comprehensive, science-based preventive controls across the food supply chain. This means that all food facilities that fall under the FSMA act must conduct Hazard Analysis and Risk-Based Preventive Controls (HARPC) and shall establish science-based preventive control measures to reduce the risk of food contamination.

The primary focus for all food processors now should be twofold:

To understand how the risk-based preventive control rules compare to HACCP principles, and,

To establish process controls in order to achieve and maintain compliance with the new FSMA law for preventing risk of food contamination.

Hazard Analysis and Critical Control Point (HACCP) and current Good Manufacturing Practices (cGMP) are essentially designed to ensure that food is manufactured, processed, packaged and stored in sanitary conditions to prevent post-process contamination in order to ensure that the food is safe, wholesome, and without visible quality deterioration.

HACCP vs HARPC

The HARPC plan has a similar concept and goal, but with a different approach.

HARPC enforces preventive controls in order to identify potential risks or threats to the food supply, and to implement appropriate corrective actions proactively to prevent contamination. The FDA has established science-based standards for conducting a hazard analysis, and implementing and documenting preventive controls.

In addition to a focus on preventive controls, HARPC requires A "qualified individual "or a "team of qualified individuals" from a facility to understand the facility's significant food safety hazards and put in place preventive controls to minimize the risk of hazards.

Although the proposed HARPC aligns well with the HACCP plan, it differs in the requirement for science or risk-based preventive controls rather than critical control points. Therefore, the establishment of critical limits would not be required under HARPC. However, the validity of preventive controls for minimizing the significant food risks should be backed up by the demonstrated or "tried and true" scientific data or authentic scientific literature. A HACCP plan is not mandatory but the FSMA HARPC is mandated by law under the FSMA act.

What hazards should be identified for HARPC?

- Biological, chemical, physical and radiological hazards
- Natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives
- Naturally occurring hazards or unintentionally introduced hazards
- Intentionally introduced hazards (including acts of terrorism)

What examples of types of preventive controls are listed in FSMA for the HARPC provision?

- Sanitation procedures at food surface contact points
- Sanitation of utensils and equipment
- Staff hygiene training
- Environmental monitoring program (for pathogen controls)
- Food allergen control program
- Recall plan
- Current Good Manufacturing Practices (cGMPs)
- Supplier verification activities

Who is exempt from HARPC?

The following categories are exempted from the HARPC plan requirement:

- Facilities under USDA jurisdiction handling, processing, and shipping - meat, poultry, eggs, etc.

HACCP vs HARPC

- Operations under the FDA's Seafood and Juice HACCP regulations
- Facilities subject to the FDA's new standards for Produce Safety Authorities. This exemption applies to farms, cooperatives, growers, harvesters and other companies handling raw fresh fruits and vegetables
- Low acid and acidified canned food processors
- Facilities defined as "small" or "very small" businesses
- Facilities with a previous 3-year average product value or revenue of less than $500,000
- Facilities that mainly produce food for animals, store raw agricultural commodities other than fruits and vegetables intended for further processing, or facilities that store packaged food not exposed to the environment for potential cross-contamination
- Facilities that are mainly engaged in manufacturing, processing, packing or holding that are considered to be low risk operations, such as shelling and hulling of almonds
- Retail food establishments, restaurants, and farms

Who needs a HARPC plan?

Any facility that manufactures, processes, packs, distributes, receives, holds or imports food must develop a HARPC plan for compliance with the FSMA HARPC compliance.

Except as exempted above, all facilities subjected to the FDA's Bioterrorism Facility Establishment registration, both in the United States and abroad, that are producing food products for distribution in the United States must develop and implement a HARPC plan that identifies risks "known or reasonably foreseeable" for each type of food subject to the regulation. The preventive controls should be adequate to "significantly minimize or prevent" identified hazards so that the food is safe. The facility must provide a HARPC plan to the FDA upon receiving an oral or written request.

When was the HARPC plan implemented?

FSMA HARPC was made into law on July 4, 2012. However, the FDA issued a proposed rule implementing the hazard analysis and risk-based preventive control provisions of the FSMA act on January 2013.

How frequently does HARPC need to be updated and submitted to the FDA?

The FDA requires that a facility update its HARPC plan every 3 years or whenever there is a significant change in the processing facility that may increase a potential hazard or introduce

a new hazard. Additionally, the FDA under the FSMA statute may require an updated plan based on unintentional or new hazards associated with biological, chemical, radiological or terrorist threats that may occur at a food facility that manufactures, processes, packs or holds food intended for human consumption.

What consequences can the FDA impose if no HARPC plan is in place or the plan is inadequate?

If a facility mandated to develop a HARPC plan does not create a plan or if the FDA inspector determines that a HARPC plan is inadequate to address threats, the FDA can:

- Issue a public warning letter and/or an import alert for a foreign supplier, effectively banning imports from such a foreign supplier. Food products from a foreign facility or supplier that is placed on the import alert would be detained at United States ports on arrival, thereby effectively barring it from entering into United States commerce until the FDA reviews and approves an updated HARPC plan.
- Criminally charge a corporation or the person in charge of a facility for failing to meet HARPC compliance.
- Suspend the facility's food facility registration, thus preventing the facility from distributing food in the US until the FDA approves the updated plan and corrective actions. This would take place if food from a non-compliant facility is found to pose a significant food safety risk.

In terms of validating process control, will the FDA be flexible in accepting tried-and-true operations or will new studies need to be conducted?

- The FDA may accept tried–and-true operations. For example, process controls such as an internal temperature of 165°F or a pH level that is less than 4.6 or a water activity of less than 0.85 have been scientifically proven to eliminate the risk of certain pathogens associated with a cook process. Trade association data or published data can also be used to show that the controls for your process have been supported by established scientific data and literature.
- New studies would be required if your process or product is new or novel and there is no scientific data or literature available to validate the effectiveness of process controls at mitigating hazards.
- Under the proposed act, the FDA will review and evaluate relevant data, at least every two years, to determine which foodborne contaminants present the greatest food safety risk and issue relevant guidance documents, regulations and preventive action levels.

Contents of a Good HACCP Plan or Manual

Basic food safety principles applied in food processing and handling are no longer enough for the modern day customer. Industry standards have far surpassed regulatory requirements. There are several reasons behind the demand of increasing levels of food safety efficacy systems. The most important: 'consumers' health is never compromised by consuming adequate food."

When achieving food safety in a product there are only positive outcomes, such as assuring part of business continuity and regulatory compliance, brand protection and customer trust. In order to assure food safety, you need to document, implement, and maintain a HACCP Plan (Hazard Analysis Critical Control Points).

UNDERSTANDING THE ELEMENTS OF A HACCP PLAN

All elements of HACCP should be set in consecutive flow so that when consulted or reviewed, everything is aligned to the methodology.

The first element in a HACCP plan is a document where all the names of the HACCP Team members are written and signed, and the team leader is clearly appointed. A brief description of each member's current position, expertise and experience should be included. A copy of a HACCP formal training certificate of at least one team member should be included. The more knowledgeable the team, the better plan will result.

The second item in the plan and manual should be a full description of the product or family of products within the scope of the plan. The description should include the recipe or formulation, when applicable. The packing materials should also be described as well as the conditions in which the product is to be stored (e.g. temperature, light, humidity) and the length of shelf life. In the description, methods of distribution should be addressed, too; taking into consideration the potential abuse in the distribution chain as well as

Contents of a Good HACCP Plan or Manual

on behalf of the consumers. The more you know your product, the better you can protect it.

The third component in the plan ought to be the identification of the intended use and consumers. Identification of the intended use must be based on the "usual" consumption of the commodity by the final consumer or user. The identification of consumers shall be based on the targeted consumer. It could be just a segment of the population, such as diabetic individuals, the elderly, infants, individuals allergic or intolerant to a certain food, immunologically compromised people, etc. The more you know your consumers, the better care you can take of them.

The fourth constituent in the plan must be the flow diagram. The diagram has to be clear and in enough detail to provide a simple description of the process steps. This diagram is very helpful to the team for future tasks and to others (e.g. customers, auditors, consultants, regulatory officials). Adding some process parameters (e.g. temperature, time, etc.) for each step could be useful, too. The flow diagram must comprehend every process step which is in direct control of the facility manufacturing the food, from the very beginning (e.g. receiving and preparing ingredients, storing packing materials, etc.) to the very end (shipping, storing, etc.). Using engineering drawing is not recommended. The friendlier the diagram is to the viewer, the easier it is to understand the process.

The fifth element in the plan should be proof that the HACCP Team has verified the flow diagram. This could be the first version of the diagram where notes have been taken and changes made, initialized and dated by the participants. Proof of the verification could also be minutes of the verification process and changes made to the original. The new verified diagram must be available. When no inaccuracies were detected in the original diagram by the verification process, a signed and dated note stating that fact shall be available. The more accurate the diagram, the more useful it'll be.

The sixth part of the plan must be the documented hazard analysis. This document must make evident the hazard significance assessment based on likelihood vs. severity. The consideration of a hazard being significant or not shall be supported by a justification. Non-significant hazards are not expected to be further considered. However, each hazard (physical, chemical or biological) found to be significant must have a linked preventive measure (e.g. GMPs, a prerequisite program) specific for its control. In the hazard analysis, it is expected to state the specific and actual hazard; and not the cause or the source of it (e.g. Salmonella, glass, sodium benzoate, etc.)

Contents of a Good HACCP Plan or Manual

The sequence of the analyzed steps has to be the same as that of the verified flow diagram. The more preventive measures, the fewer CCPs may be determined.

The seventh portion of the plan should contain documents evidencing the CCP determination process. In this document, all hazards found to be significant have to be addressed. The method used for CCP determinations shall be available, too (e.g. decision tree, questionnaire, etc.). CCPs found have to be documented.

The eighth section of the plan should contain the critical limits that were determined for each particular CCP. All the variables, values and units have to be clearly defined; for both lower and upper limits, when applicable. Documents related to the process and relevant sources used to establish the critical limits shall be available to support the limits. These documents could be regulatory standards, guidelines, internal or third party validation, experimental results, literature surveys or experts. The stricter the validated limits, the greater efficacy can be achieved.

The ninth segment of the plan should comprise of documents regarding the monitoring method for each critical limit. The monitoring procedure should contain the following: what is to be monitored? How often it shall be monitored? Who is responsible for performing the task? What instruments are to be used? How is to be monitored? The clearer the instructions are, the fewer chances of failure.

The tenth element in the plan should be the corrective actions strategy. Each CCP should have predetermined and documented corrective actions for deviations that may occur. The corrective actions plan should comprise at least the following elements: the responsibility for each action, disposition of the non-complying product, the correction of the cause of failure and recording the event. Records of events should be kept readily available. The more preparation, the less improvisation.

The eleventh component of the plan should be the HACCP Plan verification procedures. These procedures should be content activities designed to confirm that the plan is effective and properly maintained. Responsibility and frequency shall be defined. Some of the following elements should be part of the verification process: description of auditing methods, product sampling and testing, trending analysis, reviewing records and reviewing the whole plan. The more exhaustive the verification is the greater the confidence.

Contents of a Good HACCP Plan or Manual

The twelfth module of the plan should comprehend the record keeping and documentation system. In this section it should respond to the following questions? How the system is to be documented? What is to be included? Who is responsible for doing it? For how long are records to be kept? Where are they going to be kept? Who is to have access to what documents and how are those to be controlled?

A more documented plan helps with better execution.

As you may realize by now, developing and documenting an effective HACCP plan is not an easy task. Training on the methodology, experience and technical aspects are essential elements for developing and implementing an effective HACCP Plan. External help and consultation is often required in order to succeed in this endeavor. In such case, Safe Food Alliance has the right people with the right knowledge and expertise to assist you. At Safe Food Alliance we provide a recognized HACCP training, consulting and verification services.

How To Make HACCP Work For You

As mentioned already, HACCP promotes safe food by attempting to avoid hazards in production. This is accomplished, primarily, through seven principles:

Conduct a hazard analysis – Begin by reviewing every step in the entire manufacturing process (from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product) and consider the potential risks for biological, chemical, and physical contamination. Once those risks are identified, a HACCP management plan calls for controlling the hazards by identifying and implementing preventive measures.

Not sure how to conduct a hazard analysis? Joining Safe Food Alliance for an in-person training course taught by highly knowledgeable trainers who audits systems like yours.

1. Identify critical control points (CCPs) – In many manufacturing environments, there will be one or more points in the process where a failure of Standard Operating Procedures (SOPs) has both a significant chance of occurring and causing harm to a consumer. At such a point, a CCP is established as a process to control the hazard and prevent, eliminate, or reduce the hazard to an acceptable level.
2. Establish critical limits for each critical control point – One of the defining factors of a CCP is that the process has measurable results. Every CCP will have a critical limit: the maximum or minimum value that reliably prevents, eliminates, or reduces a hazard to an acceptable level. In some processes, the critical limit might be a measure of water activity (aw) that prevents microbial growth, or a measure of time and temperature that represents a 5-log reduction in pathogens, such as

a juice achieving 160°F for 6 seconds. Don't forget that critical limits must be science- and evidence-based.

3. **Establish critical control point monitoring requirements** – After identifying your CCPs and establishing critical limits, you will need to develop and implement a method for monitoring your CCPs. You will need to determine an effective way and frequency to measure your CCP to ensure that it remains within critical limits. Monitoring CCPs will help you to observe when your process is trending out of control so that you may make corrections to keep it in control. Monitoring will also ensure you know if your process has gone out of control by deviating from the critical limit, alerting you that the product is at risk and needs corrective actions. Your monitoring records will also be of critical importance to your verification of the HACCP system.

4. **Establish corrective actions** – Although the HACCP management system is meant to prevent hazards, there are occasions in which the actual process deviates from the plan. With this possibility in mind, a facility must develop corrective actions that will help keep potentially hazardous food away from consumers.

   A corrective action will entail:

   - Determining and correcting the root cause of the deviation
   - Determining the disposition of the affected product
   - Keeping a record of the corrective action(s) taken

   A thorough HACCP plan will include instructions on what to do in the case of a deviation, the person(s) responsible for implementing corrective actions, and requiring that the deviation and corrective action be recorded.

5. **Establish verification procedures** – HACCP management plans depend heavily on good science to produce safe food. This has an impact on the development and maintenance of a HACCP plan in two key ways:

   The development of the HACCP plan must be based on good scientific evidence in identifying and controlling for risks. For instance, a CCP that is meant to reduce a hazard to an acceptable level should be based on scientific studies (such as those that indicate the cook time and temperature for a

For extra help, read the article "Writing Corrective Actions for Your Food Safety Audit". **CHECK IT OUT**

5-log reduction of pathogens in a type of product in general) and verification that the controls in place in your particular facility and process are effective.

Your HACCP plan should be routinely verified to ensure that it is effectively preventing and controlling hazards and that it is being followed and applied consistently. This is generally accomplished both through periodic internal audits and external third-party audits.

Need to create an internal audit program? Our self-paced online Internal Auditor course offers easy to understand audit training to help you verify the effectiveness of your food safety system.

6. **Establish record-keeping and documentation procedures** – If the rest of your HACCP plan involves you saying what you will do and doing what you say, the seventh principle requires you to keep records documenting that you do just that. Clear, consistent records make it possible to demonstrate that the food you manufacture was produced safely.

   These will not only be production records but will also include items relating to all of the previously mentioned principles. A good record-keeping system will make it possible for an outside auditor like the ones at Safe Food Certifications to easily understand your HACCP plan, the evidence supporting your CCP identification and critical limits, and to see what your plan has looked like in action.

As previously stated, HACCP is the foundation for food safety. It is important to not only take the time to learn it but also see its value. With an effective food safety system, your facility will become more efficient, lower the likelihood of recalls, and save you money long-term. With the ever-increasing regulations and expectations from consumers, HACCP is the best choice for anyone in the food industry.

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NEXT STEPS

GET HACCP TRAINING

These trainings can be offered either as onsite programs, online training, or as public courses. If you would like to suggest a public training or request a quote for onsite training, contact our food safety team at **foodsafety@safefoodalliance.com** and we'll get back to you as soon as possible.

These courses are accredited by the International HACCP Alliance as meeting the required standards for content and training for HACCP.

FIND AN UPCOMING PUBLIC COURSE NEAR YOU!

HACCP VERIFICATION

Safe Food Certifications is proud to be the sole provider of the DFA Food Safety Standard v10.6/HACCP Verification Audit. The HACCP Verification Audit can satisfy the third-party food safety certification requirement of some customers, can serve as a way to verify a facility's continued commitment to food safety, and can be a valuable tool in preparing for GFSI certification.

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NEXT STEPS

The Safe Food Alliance Food Safety Standard groups into three major sections of increasing food safety system development:

Prerequisite Programs

Implemented procedures and practices, which reduce the occurrence of food safety hazards.

Good Manufacturing Practices (GMP's)

Good Manufacturing Practices (GMP's) ensure that food products are manufactured, packaged, and stored in a sanitary manner. When formally documented and implemented, GMP's are an example of a prerequisite program.

Hazard Analysis and Critical Control Point (HACCP)

Hazard Analysis and Critical Control Point (HACCP) systems utilize prerequisite programs and GMP's as the foundation for a risk-based approach in controlling food safety hazards.

Wherever you are on your food safety journey, Safe Food Certifications has a team ready to answer your questions and help you prepare for your next audit. Please reach out to us if you would like to request an audit or if you have any questions about certification.

REFERENCES & RESOURCES

Codex Alimentarius for Food Hygiene

Food Safety Modernization Act