intertek
alchemy

The Comprehensive Guidebook to Successful HACCP Systems

Table of Contents

Hazard Analysis and Critical Control Points (HACCP) has been the internationally accepted approach to food safety for over six decades. From its conception in the 1960s by Pillsbury and NASA to an endorsement by the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) and CODEX, HACCP has become the central theme for the basis of U.S. Department of Agriculture (USDA) regulations, U.S. Food and Drug Administration (FDA) regulations for seafood and juice products, and Global Food Safety Initiative (GFSI) standards. HACCP is so much a part of conventional food safety plans that it will continue to be the most commonly accepted approach for food safety management, even as alternative methods such as the FDA Food Safety Modernization Act Preventive Controls for Human Food and Canadian Food Inspection Agency Preventive Control plans have been established. **The 12-step HACCP approach with the 5 preliminary steps and the 7 principles of HACCP provides a sound methodology for food safety when successfully implemented**.

Identifying the Problem

If HACCP is so great, why does the food industry continue to fight unacceptable levels of foodborne illness outbreaks and product recalls year after year? There are three primary flaws in the HACCP approach that have caused continued failures in food safety systems.

First, companies typically only identify a minimal number of Critical Control Points (CCPs), leaving many potential hazards to be controlled by prerequisite programs (PRPs) such as sanitation, allergen control, foreign material control, supplier management, and many others. However, PRPs are not addressed specifically in the 5 preliminary steps or 7 HACCP principles, so they do not really receive the importance and attention they deserve. More often than not, failures of key PRPs lead to foodborne illnesses or recalls and range from inadequate sanitation controls causing environmental pathogen contamination or labeling issues for allergen control.

Second, the Hazard Analysis principle does not require any type of quantitative risk assessment for the likelihood and severity of the hazards identified. Most Hazard Analysis worksheets simply ask questions requiring only a Yes/No answer, such as "Is the hazard reasonably likely to occur?" or "Is the hazard significant?" In most cases, companies answer these questions with a No, then cite a PRP to justify not making the process step a CCP. Once again, the PRP doesn't really get the attention it deserves to ensure control over the hazard identified. No limits, no monitoring, no verification, and no recordkeeping equal no process control.

A quantified risk rating system would require an adequate assessment of the hazard and eliminate the excuse of not being likely to occur due to PRP controls.

Third, HACCP system validation is not often adequately performed or understood since it is buried in the HACCP verification principle. Proper HACCP validation would ensure that the correct hazards have been identified, based on the raw materials, finished products, and manufacturing processes used and that the correct CCPs and critical limits have been identified to control the hazards. Most companies simply do not understand HACCP validation or they don't take the time to do it thoroughly.

Many people believe the NACMCF should designate HACCP validation as the eighth principle of HACCP. In recent years, USDA required all meat and poultry establishments to revalidate their HACCP systems. They published a helpful HACCP Systems Validation Guideline detailing the two elements of validation for not only CCPs but also PRPs with critical operational parameters. Unfortunately, the validation requirement was not well enforced, so most establishments still did not effectively validate their HACCP systems according to the guideline. **Effective HACCP validation that assures hazards are properly identified and controlled is critical to preventing foodborne illnesses and product recalls.**

Implementing a Foundation for HACCP

What does it take for HACCP systems to be really successful? Before you get to the 12-step process, **there must be a solid foundation of management commitment, food safety culture, and PRP control.** When we teach food safety courses, we always discuss the necessity of having a strong foundation for the HACCP system before you apply the 12 steps. Just as a weak foundation will not support a house's walls and ceiling, a weak foundation in your food safety system will lead to cracks that cause illnesses and recalls.

Successful HACCP systems **start with management commitment at the top** to set the expectation for nonnegotiable food safety and provide the resources needed for personnel, training, and capital expenditures. This commitment must cascade down all levels of the organization so that food safety comes first as top priority. In addition, a positive food safety culture must permeate the organization until every employee is committed to doing the right thing every time, no matter who is looking. **Food safety culture should be assessed and continually improved.**

PRPs include supply chain management, sanitation, Good Manufacturing Practices, allergen control, pest control, foreign material control, training, maintenance, calibration, storage and transport, water potability, and waste management. These programs have a huge impact on food safety; however, they are rarely controlled with CCPs in HACCP plans other than perhaps metal detection. Establishments should reconsider the risk assessment of hazards controlled by these programs to assess whether any should be potentially elevated to CCPs, particularly for allergen, sanitation and supply chain controls. Key PRP control points should still have operating limits, monitoring, corrective action, verification, and recordkeeping procedures to establish process control.

Taking the Preliminary Steps

When a strong foundation is in place, you are ready to move on to the 5 preliminary steps of HACCP. These five steps along with key points for each included in Table 1.

TABLE 1: Five Preliminary Steps of HACCP

Step	Activity	Key Points
1	**Assemble the HACCP team**	"Team" is the key word. Have representatives from all departments. Make decisions together. Meet regularly. Don't do it by yourself.
2	**Describe the food and its distribution**	Know key safety attributes of the products, such as temperature requirements, pH, water activity, and moisture levels. Validate shelf life. Be careful grouping products in categories.
3	**Describe the intended use and consumers**	Know who is using the product. Define sensitive populations such as school lunch, hospitals, and nursing homes. Consider intended and foreseeable uses of the products.
4	**Develop the flow diagram of the process**	Include all key process steps for raw materials, ingredients, and packaging materials. Don't forget rework and returned product. Consider all inputs including water, ice, air, gasses, and processing aids. Number the steps to correlate with the hazard analysis.
5	**Verify the flow diagram of the process**	It is critical to walk the floor to verify each step. Look for missing or overlooked process steps. Have the entire HACCP team perform this step and sign the flow chart for verification.

Knowing & Understanding the HACCP Principles

The 7 principles of HACCP along with key points for each included in Table 2.

TABLE 2: Seven Principles of HACCP

Step	HACCP Principle	Key Points
1	**Conduct a Hazard Analysis**	Address biological, physical, and chemical hazards for every step in the flow chart. Thoroughly assess if the hazard is reasonably likely to occur. Provide proper justification if not. Complete separate process Hazard Analysis for each step on the flow chart and ingredient Hazard Analysis for each raw material used. Consider using a quantitative risk assessment methodology with specific assignments for risk and severity and overall risk rating for each hazard identified
2	**Determine the CCPs**	Control all reasonably likely to occur hazards with a CCP. Identify the right CCPs where control can be applied and hazards can be controlled.
3	**Establish critical limits**	Assure limits will control hazards identified. Validate with regulations or scientific supporting documentation. Cite validation references.
4	**Establish monitoring procedures**	Define the what, how, frequency, and who. Meet minimum frequencies defined in the HACCP plan.
5	**Establish corrective actions**	Address all regulatory requirements to identify and eliminate the cause, bring CCPs under control, take preventive measures, and ensure no adulterated product enters commerce. Include a direct observation of corrective actions.
6	**Establish verification procedures**	Understand the differences between CCP verification (record review, calibration, and direct observation), HACCP plan verification through reassessments , HACCP validation, and regulatory verification. Address all four elements in your HACCP system.
7	**Establish recordkeeping procedures**	Define titles of all forms used associated with the CCPs. Train personnel how to record all required information.

Avoiding Mistakes

When Certification Program Owners (CPOs) such as SQF, BRCGS, and FSSC 22000 report their lists of Top 10 Non-conformances each year, issues with the HACCP Plan are consistently identified in this Top 10 list. In addition, major retailers are pushing back against the Global Food Safety Initiative (GFSI) and the CPOs, citing suppliers are not effectively implementing HACCP and Food Safety Plans to reduce their risks of recalls. The most frequent nonconformities include inaccurate or unverified flow charts, incomplete or insufficient Hazard Analysis, ineffective implementation, and inadequate HACCP plan validation.

Below is a list of common mistakes observed in HACCP Plans and ways to avoid them.

All process steps are not included on the flow charts, including rework, recouped product, returned product, water, ice, compressed air, gasses and processing aids.

Be sure the entire HACCP team verifies the flow chart with an annual plant walk-through (at minimum) to ensure that all steps are properly included.

Hazard Analysis worksheet steps and flow chart process steps do not correlate.

Each step on the flow chart should be in the Hazard Analysis, and vice versa. Numbering the steps on both will help prevent this mistake.

Correct biological, physical, or chemical hazards specific to the type of pathogens or foreign materials of concern are not identified or specified.

It is critical to identify the right hazards based on the raw materials, finished products, and manufacturing processes used. The specific pathogens of concern should be identified, rather than just stated as pathogens, so the correct limits can be identified to control the hazards as part of the validation process.

Too many or too few CCPs are identified.

Establishments tend to want to identify as few CCPs as possible for regulatory reasons; however, your HACCP plan should be based on scientific HACCP to identify and control hazards as needed to assure food safety. At the other extreme, you don't want too many steps to be CCPs so that it reduces the emphasis on the key steps necessary for food safety control.

CCP procedures in HACCP plan summaries are not fully defined for monitoring, corrective action, verification, or recordkeeping procedures.

The HACCP plan summary is one of the most important documents in the HACCP plan. Monitoring procedures must be specific to detail what is being monitored, how it is being monitored, how frequently it is being monitored, and who is responsible for monitoring. Corrective action procedures must be specific to address the product disposition, correct the cause of the deviation, establish preventive measures, and assure no adulterated product enters commerce. Verification procedures must include record reviews, calibration procedures if applicable, and direct observation of monitoring in USDA establishments. Independent checks are a great best practice to include as part of the verification procedure.

CCP records are insufficient due to not being complete, accurate, or timely to capture all monitoring and verification information required.

Monitoring personnel must be taught how to record results and initiate corrective actions when necessary. Record reviews need to be performed thoroughly after the record is fully complete and not pencil-whipped with a signature at the bottom. The person reviewing the record needs to assure limits have been met, monitoring has been performed at the frequency required, and all required information is on the form and accurate. Personnel signing monitoring and verification tasks must remember these are legal documents and assure the integrity of the information recorded and their name.

HACCP plan reassessments are not completed when necessary, especially for raw material, finished products, or equipment changes between annual reassessments.

For Cause Reassessments need to be completed each time a significant change is made to assure the nature of the change, the impact on the HACCP system and changes made to the HACCP Plan as a result of the change. Be sure to document a complete review of the entire food safety system at least annually. This full HACCP System reassessment should include four major components including a review of the written HACCP Plan and PRP to assure everything remains accurate, a plant audit of CCPs, operational sanitation and pre-operational sanitation, an extensive record review of 60-90 days of records to assure consistent implementation and a review of any product and environmental testing results. A HACCP Plan Verification and Reassessment Report should be documented to summarize the written programs reviewed, plant audit results, record review results and testing results then list changes made to the plan as a result of the reassessment and statement the HACCP Plan has been reassessed and verified to be current and accurate.

HACCP plan validation scientific data or validation reports is insufficient.

Take time to thoroughly validate your HACCP system. Have supporting documentation on file to justify the hazards identified, CCP process step selection, and critical limits. The HACCP Plan Validation Data should be summarized to list the CCP, Critical Limits, Critical Operating Parameters and the Scientific Supporting Documentation and/or Regulatory References justifying the critical limits. USDA establishments must also document the Element 2 Internal Validation Requirements with the record review periods and test results summary. USDA establishments must also have supporting documentation on file to justify monitoring and verification frequencies.

Ensuring Compliance

From an implementation perspective, companies struggle most with monitoring and recordkeeping procedures. Employee turnover makes it a challenge to keep competently trained people on monitoring and verification tasks. It is crucial to select responsible individuals to perform these tasks. Depending on the company culture, you must decide which roles will do each. Successful companies often have operations personnel perform monitoring tasks since they own the process, and quality assurance personnel perform verification tasks. The downside to this approach is that it increases the number of people keeping records and thus the potential for mistakes. However, proper training and the right culture can mitigate this risk. Companies should be careful to write HACCP plans in a way that decreases risk of noncompliance. For example, instead of defining a monitoring frequency of "every hour" which locks you into a 60-minute window, you could use the term "once in each hour time frame" so you now have 120-minute window to perform monitoring. Flexible yet compliant language is key to a successful HACCP system.

HACCP records are legal documents. **It is imperative to fill records out in a complete, accurate, and timely manner.** People are currently in jail due to falsifying HACCP records. Training is of the utmost importance for responsible individuals to know how to complete HACCP records. Examples of frequent recordkeeping issues include prerecording times or other information, missed monitoring or record review checks, illegible initials or signatures, or failure to properly document corrective actions. Effective record review processes assure products are safe prior to sending them into commerce and it reduces risk of regulatory nonconformances.

Performing HACCP Reassessments

Your HACCP system should be a living, breathing document that stays continually up-to-date to reflect your current operations. Annual HACCP reassessments are required by regulations and GFSI audit standards. The annual reassessment process should include four major parts:

1. **Review of all written programs** [HACCP, Sanitation Standard Operating Procedures (SSOPs), and PRPs] to ensure they are still up to date and accurate
2. **Plant audit** of CCP process steps, preoperational sanitation, and operational sanitation
3. **Record reviews** of 60-90 days depending on plant size of records to review completeness, effectiveness of corrective actions, and trend analysis for key attributes
4. **Review of microbiological test results** for product and environmental testing

At the completion of the reassessment process, you should document the results in several places: first, in a reassessment checklist to show what has been evaluated; second, in a reassessment report to document the dates, personnel involved, HACCP plans assessed, and changes made as a result of the reassessment; and third, in a HACCP validation report to summarize the CCPs, PRP critical operational parameters, limits associated with each, and the regulatory standards or scientific studies referenced to demonstrate the effective control of hazards identified.

In addition to the annual reassessment, HACCP plans should also be reassessed:

1. **When significant changes occur** for new equipment, raw materials, formulation changes, finished products, and suppliers
2. **When CCP failures occur** to identify changes and preventive measures needed
3. **When unforeseen hazards occur** that had not previously been considered during the hazard analysis process
4. **When you become aware of new information** related to industry or regulatory events that may have an impact on your operations

These reassessments should also be documented to assess the impact of the change and determine whether changes need to be made to the HACCP plan product description, flow chart, Hazard Analysis, or HACCP plan summaries.

Measuring Successful HACCP Systems

HACCP systems should have metrics to prove they are working and demonstrate continuous improvement over time. GFSI standards require you to set specific objectives for your food safety and quality management system. Objectives could be set for key performance indicators such as seen in Table 3.

As you can see, there are many ways to evaluate the effectiveness of your food safety systems. You have to decide which ones are applicable to your operation, set specific goals, and then measure your results on a regular cadence, such as monthly or at least quarterly. Formal management review meetings should be conducted routinely to consider inputs, review results, and determine outputs necessary to drive continuous improvements. Minutes of these meetings should be well documented and made available to auditors upon request.

TABLE 3: HACCP Key Performance Indicators (KPIs) Objectives & Goals

Objective / KPI	Goal
Food Safety Recalls	Zero Tolerance
CCP Deviations	< targeted quantity of occurrences
3rd Party Audit Results	Zero HACCP/FSP nonconformities
Internal Audit Results	Number of nonconformances identified or score
Microbiological Results (Product/ Environment)	Percentage within target levels
Corrective & Preventive Actions (CAPA)	< number of incidents and completion or improvement over baseline
Customer Complaints	Targeted % improvements over baseline results or < number of targeted complaints
USDA Noncompliance Records or FDA Enforcements	< targeted number of records or targeted % improvement over baseline results
Nonconforming Product (Internal and Suppliers)	Number of incidents, volumes, and targeted improvements over baseline results

Objective / KPI	Goal
SSOP Results	Number of deficiencies and targeted improvements over baseline results
Food Safety Culture Communications	Target minimum number of Employee Feedback Forms received
Food Safety Culture Training Completion	% of targeted Training completed
Food Safety Culture Assessments	Assessment Results and Continuous Improvement
Food Safety Culture Turnover	% employee turnover rates compared to past periods

Sustaining Successful HACCP Systems Conclusion

Ongoing HACCP team meetings on a quarterly basis are a great way to sustain your HACCP systems. Rotating members of the HACCP team helps to bring in fresh ideas and increase sponsorship for the food safety system. HACCP team meetings, management review meetings, and effective HACCP plan reassessments are the keys to successfully sustaining your HACCP system.

In conclusion, your efforts to assure safe products through HACCP systems make a great contribution to society by preventing foodborne illnesses. Let us always remember this is what makes our jobs worth doing. For all the unsung heroes in the world of food safety, we applaud your relentless efforts to make our food supply safe and our world a better place.

Help Is Here If You Need It

We hope this guide is helpful as you work to bolster your food safety system. If you would like further assistance, or simply want an outside perspective to review your work, we are here to help. Please don't hesitate to utilize any of these resources:

Ask a Question

If you have a question about anything in this guidebook, you can reach the authors at **Consulting@IntertekAlchemy.com**.

Consulting Services

Even FSQA experts benefit from outside, independent review. The Intertek Alchemy food safety consulting team is available for every level of assistance you require. Submit a request form on this page to get started: **IntertekAlchemy.com/Content/Food-Safety-Consulting**.

Online HACCP Certification

Learn from the authors of this guidebook and earn your HACCP Certification through these self-paced eLearning courses. You will receive an official certificate from the International HACCP Alliance upon completion. **ZosiLearning.com/Courses/Food-Safety/HACCP**.

intertek alchemy