TRACEGAINS

# A Step-By-Step Guide to Implementing a HACCP Plan

# A Step-By-Step Guide to Implementing a HACCP Plan

Compliance is an imperative element of the food industry, yet decoding and implementing regulations can be challenging. This practical guide takes you step-by-step through developing your own hazard analysis critical control point (HACCP) plan and putting it to work in your facility. It's based on the 12 steps and seven principles of Codex and is easy to understand and apply to your own food plant. It's a great foundation for any GFSI-benchmarked certification audit.

A HACCP plan is a logical, scientific system that helps control safety problems in food production. Some of these hazards may be related to personnel, operations, or to the environment and are controlled by Good Manufacturing Practices (GMPs), the operator, or the supplier. Additionally, some hazards might need a new method, procedure, or machine to eliminate or reduce them. HACCP is a requirement for most food companies, and implementation of a risk-based HACCP is a fundamental requirement for all Global Food Safety Initiative (GFSI) schemes. HACCP also serves as the foundation for the Food Safety Modernization Act's (FSMA) Hazard Analysis and Risk-Based Preventative Controls (HARPC).

Codex Alimentarius, or "Food Code" is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission. The commission is a joint intergovernmental body of the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) with 188 member countries and one member organization (the European Union).

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# How do you start building your HACCP plan?

To have a successful HACCP plan, you need to have comprehensive knowledge of:

- Incoming materials and country of origin
- All products
- Food safety characteristics
- Processes
- Treatments
- Packaging methods
- Shelf life
- Storage conditions
- Intended use

All areas of the plant, including restrooms, lunch areas, and hand-washing stations, should be familiar to the team, and employees must always be aware of the activity taking place in each area. Additionally, the movement of people, ingredients, packaging materials, chemicals, wastes, processing aids, allergens and finished product, and their associated hazards around the facility, must be known.

Systematic gathering and analysis of information is required to determine hazards, including critical control points (CCPs), and to ensure the proper control measures are applied.

Definition of a hazard: A biological, chemical or physical property that may cause the food to be unsafe for consumption by the consumer.


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STEP 1

# Designate a HACCP Team

The role of the HACCP team is to develop, manage, and implement the HACCP plan. The team should be multi-disciplinary, representing individuals from all areas of the facility. For example, include representatives from QA, R&D, sanitation, management, maintenance, and other necessary departments to help bring in knowledge and various points of view from different areas of the operation.

Together, the team must have knowledge of how the business works, how products are produced, what could/has gone wrong, and food safety compliance requirements. The HACCP Coordinator is usually the point person for the HACCP Plan. If you don't have a HACCP Coordinator within your organization, then your Quality Assurance Manager or even CEO may be the appropriate person for that responsibility. Once the team is assembled, it's important to include a complete training program on HACCP so the team is clear on the steps and principles required.

It's expected that the HACCP team will define the scope of activity, lead hazard analysis, be called upon when re-evaluation is necessary, and will work collaboratively with all facility employees to ensure the HACCP is a living, well-executed program. Another important activity of this team is to document all meeting activities, training, and decisions for future reference.

To assemble the team:

- Assign a HACCP Leader with a HACCP training certificate and experience in the field.
- Team members can include: Quality Assurance Manager, Plant Operations Manager, Engineering Manager, Maintenance Manager, Sanitation Manager and/or Supervisor, Shipping & Receiving (Warehouse) Manager and/or Supervisor, Line Supervisor and/or Machine Operator.
- If you have a consultant, include them as a secondary member.

If you don't have a HACCP Coordinator within your organization, then your Quality Assurance Manager or even CEO may be the appropriate person for that responsibility.

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STEP 2

# Product Description

Next, you will need to ask for the products to be described. Once a full description of each product is obtained, you'll need to group products into the HACCP plan according to similarity of processing steps, food safety controls, and the composition and nature of finished products.

The product description should include a list of all products covered by the HACCP plan. Each of these products may be a product family with similar ingredients. New products to be included in a HACCP plan must be reviewed for compatibility with the plan before production; and, if compatible, should be added to the product list in HACCP documentation before production. Obsolete products should be removed from the list in a timely manner. Individual stock keeping units (SKUs) don't need to be listed in HACCP documentation, however a method of cross-referencing products in the HACCP plan with SKUs must be readily available.

Product Description Elements:

- Relevant safety information
- Finished product recipes
- Ingredients
- Processing aids
- Packaging material
- List exporting countries
- Allergens
- Restricted ingredients (food additives like aspartame, caffeine, etc.)
- Country of origin
- Vulnerable ingredients

Any treatments or processes influencing product shelf life should also be listed in this step. For example, the product may be raw, cooked, or ready to eat and/or pasteurized, or vacuum packed. The type of product should indicate storage requirements and how consumers should consume it. When you're collecting information for ingredients in the certificate of analysis (COA), make sure to include all subcomponents. If you're required to perform vulnerability assessments as it relates to food fraud, you'll need to dig a little deeper to find whether there are secondary or tertiary suppliers for vulnerable ingredients (olive oil, fish, organics, etc.). If the ingredients include subcomponents, make sure you know all the suppliers involved.

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STEP 3

# Identify the Intended Use of Finished Products

The intended use of the product refers to its normal use by end-users or consumers. The HACCP team must specify where the product will be sold, as well as the target group, especially if it happens to be a sensitive portion of the population (i.e. elderly, immune-suppressed, pregnant women, and infants).

Keep these points in mind when identifying intended use:

- Retail
- Food service
- Further processing
- General public
- Vulnerable population
- Will the food be heated by the consumer?
- Will there likely be leftovers?

If the food will be heated, there needs to be instructions for the consumer, and these also need to be included in your HACCP plan.

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STEP 4

# Construct a Process Flow Diagram

You must show all the steps in a manufacturing process for a product or group of products. The reason for this flow diagram is to have a clear and simple outline of the steps involved in the processes, the sequence of production, and how different parts of the process are interacting with one another. This clear view of processing steps is very helpful when conducting a hazard analysis.

The flow diagram should include:

- Receiving ingredients
- Packaging materials
- Storage of ingredients
- Process steps
- Process step numbers
- Recycle and rework products (work in progress should also be marked along with the materials used)
- Introduction of packaging materials
- Introduction of air, water, and steam
- CCP
- Outsourced processes and subcontracted work
- Process parameters
- Potential for delay
- Finished products
- Intermediate/semi-processed products
- Byproducts
- Low/high-care/high-risk area segregation

Include all process flows that impact food safety, such as employee traffic patterns and waste flow in the HACCP. Additionally, identify any areas that require extra precaution or special treatment. For example, if you're a gluten-free processing plant, the lunch room might also need to be a gluten control area.

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STEP 5

# Verify Flow Diagram

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. This ensures the flow diagram is an accurate representation of the operations. The team should confirm the flow diagrams are accurate with on-site audits and challenges at least annually. However, daily and seasonal variations need to be considered and evaluated. It's important that verification of flow diagrams is recorded and maintained.

How to Verify Your Flow Diagram

1. Print a copy of your HACCP flow process charts.
2. Walk around your food production facility and check if the steps you've documented on your HACCP flow process charts reflect reality. It's helpful to start at the beginning of a process.
3. If you find there are steps missing, additional steps or steps documented in the wrong order, make notes of these as you walk around.
4. Make updates to the controlled versions of your HACCP flow process charts.

Note: It's a good idea to have all members of your HACCP team complete this process individually to ensure different perspectives and that nothing is missed.

Make sure:

- Flow diagrams are verified by the HACCP team.
- All shifts have been verified.
- Sign and date the flowchart for records and documentation.

During an external audit, you'll be required to show proof you've verified your HACCP flow process charts.

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STEP 6

# Conduct Hazard Analysis

By this point in your HACCP plan you've gathered all finished product information. This is necessary to carry out step six, which is to develop a list of significant hazards reasonably likely to cause injury or illness if not effectively controlled.

These potential hazards can be:

- Biological
- Chemical
- Physical
- Allergen-related
- Irradiation-related

A detailed hazard analysis is key to preparing an effective HACCP plan. If the analysis isn't performed correctly, the plan won't effectively control the unknown hazard, which results in an ineffective HACCP plan. Remember, if hazards happen once, they're likely to happen again.

**Risk Assessment**

For each identified hazard, the risk should be analyzed. To conduct your assessment, look for:

- Each identified hazard
- Likelihood of occurrence
- Severity
- Risk level

Effectively identify specific potential hazards associated with each processing step through the completion of a hazard analysis. This analysis considers the likelihood and severity of hazard occurrence and the measures that can be applied to control the identified hazards.

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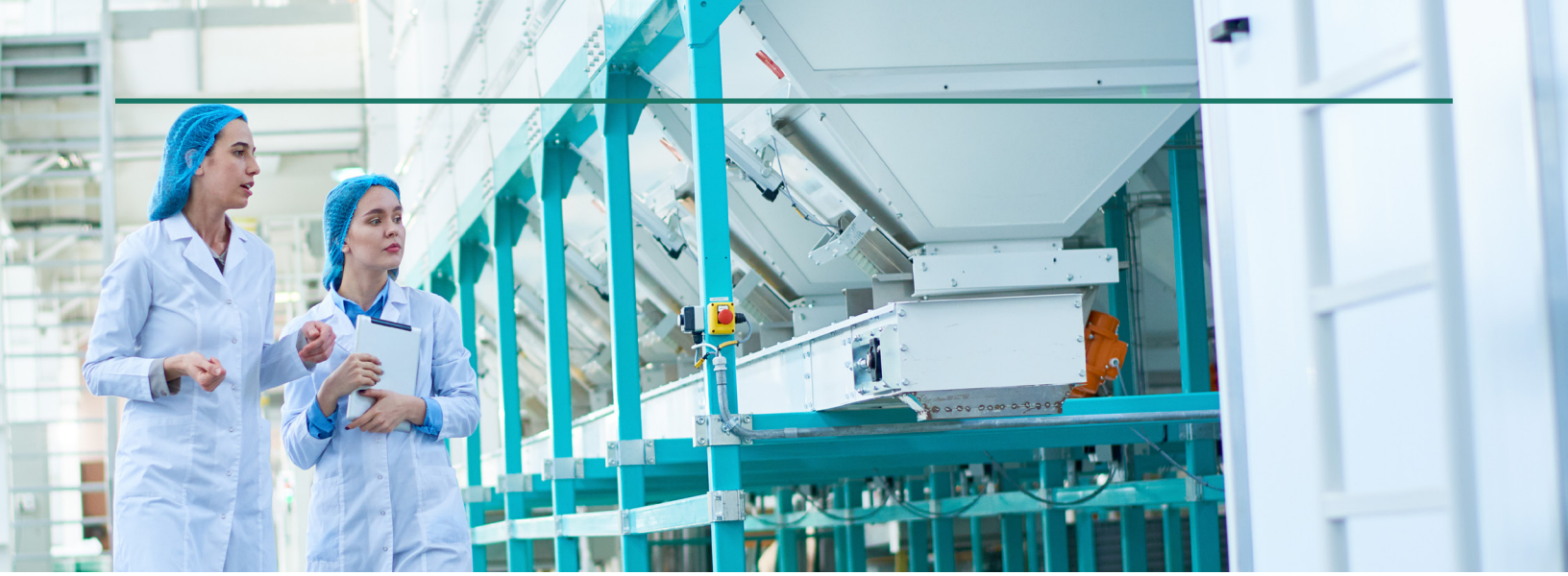

STEP 7

# Critical Control Points Identification

After conducting the analysis, you need to identify critical control points (CCPs), allowing a control to be applied to prevent, eliminate, or reduce any potential risk. To determine your CCPs, you'll need to ask a series of yes or no questions, which will ultimately inform you if the step is critical or not.

One strategy to facilitate the identification of each CCP is the use of a CCP decision tree. Keep in mind that a decision tree is merely a tool; it is not a mandatory element of HACCP, nor is it a substitute for expert knowledge.

Examples of CCPs may include:

- Chilling
- Thermal processing
- Product formulation control
- Testing ingredients for chemical residues
- Testing product for metal contaminants

For example, Salmonella and Listeria are both bacterial pathogens whose presence may be unpredictable from batch to batch in food production. If their level is high or unpredictable, then these pathogens constitute a hazard for the food manufacturer. Therefore, a CCP for these hazards would be a heat-inactivation step. If such heat inactivation were extensive enough to kill 99,999 out of 100,000 cells, then killing efficiency would be 99.999 percent or a so-called five-log kill. This kind of critical control point is defined as "pasteurization."

CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. Different facilities preparing similar food items can differ in the hazards identified and the CCP steps. This can be due to differences in each facility's layout, equipment, selection of ingredients, processes employed, etc.

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STEP 8

# Critical Control Limits Identification

A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce the occurrence of a food safety hazard. While CCPs are the last place a company can control for food safety hazards, critical limits must be set to ensure food safety hazards are eliminated or reduced and maintained at acceptable levels.

These limits are essential criteria to control hazards:

- Separate safe from unsafe products
- Maximum or minimum value
- Control potential hazards
- To prevent, eliminate or reduce physical, chemical and biological hazards

Critical limits must be scientifically based. For each CCP, there's at least one criterion for food safety that's to be met. The critical limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results, and experts.

"Depending on the product, each CCP may have multiple physical, chemical, and biological critical control limits that need to be established. Temperature, for example, is a common element that needs to be controlled to stop biological food safety hazards." Donna Schaffner, independent HACCP consultant microbiologist and the Associate Director of Food Safety, Quality Assurance and Training for Rutgers Food Innovation Center

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STEP 9

# Establish Monitoring Procedures

This step is used to establish monitoring standards for each CCP. The monitoring program is made up of physical measurements or observations that can be done quickly, to provide the information in a time frame that allows you to take immediate action when an out of control situation occurs. The food safety team must identify appropriate monitoring for each critical control point. The monitoring must be designed to monitor the specific hazard that's being controlled at that point. The method should provide an early warning if a process is losing control, and warn if a critical limit has been exceeded.

Monitoring serves three main purposes:

1. It facilitates tracking of the operation. If monitoring indicates there's a trend toward loss of control, then action can be taken to bring the process back into control before a deviation occurs.
2. It's used to determine when there is loss of control and a deviation occurs at a CCP (i.e., exceeding or not meeting a critical limit). When a deviation occurs, an appropriate corrective action must be taken.
3. It provides written documentation for verification.

It's important to identify the appropriate measuring equipment, responsibilities for measuring or observation as well as training and qualifications of those responsible. The plan must address how data will be recorded, reviewed, and analyzed. The location of the monitoring is also a key element. It must take place exactly where the hazard is being controlled.

When setting monitoring procedures, ask:

- What should be monitored?
- How should it be monitored?
- At what frequency should it be monitored?
- Who should be doing the monitoring?

The location of the monitoring is also a key element. It must take place exactly where the hazard is being controlled.

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STEP 10

# Establish Corrective Actions

Those versed in ISO 9000 quality processes are familiar with two major types of actions, corrective being one, preventative being the other. The HACCP plan focuses on corrective actions. When there's a deviation from the established critical limits, corrective actions are necessary to prevent unsafe foods from reaching consumers. Step 10 in implementing a HACCP plan is to establish these corrective actions.

The FDA's guidance on the required steps for a Corrective Action:

1. Determine and correct the cause of non-compliance
2. Determine the disposition of non-compliant product
3. Record the corrective actions that have been taken

The FDA requires the HACCP plan to specify what's done when a deviation occurs, who's responsible for implementing the corrective actions, and that actions are recorded and maintained. Individuals who have a thorough understanding of the process, product, and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of the non-compliant product. To add to this, the documentation should contain a description of the non-conformity plus analysis and determination of the root cause.

Corrective Action Definition: Action to eliminate the cause of a detected nonconformity or other undesirable situation.

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STEP 11

# Determine Verification Procedures

Once you have critical limits and corrective actions in place, you need to verify these procedures to determine if the HACCP system is effective. Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and the system is operating according to the plan.

One aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end-product testing, since enough safeguards are built in early in the process. Therefore, rather than relying on end-product testing, you should rely on frequent reviews of their HACCP plan, verification the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records.

Another important aspect of verification is the initial validation of the HACCP plan to determine the plan is scientifically and technically sound, all hazards have been identified and, if the HACCP plan is properly implemented, these hazards will be effectively controlled.

Verification procedures may include:

- Establishment of appropriate verification schedules.
- Review of the HACCP plan for completeness.
- Confirmation of the accuracy of the flow diagram.
- Review of the HACCP system to determine if the facility is operating according to the HACCP plan.
- Review of CCP monitoring records.

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STEP 12

# Recordkeeping

The last step in creating your HACCP plan is to establish recordkeeping and documentation procedures. Recordkeeping is not only required by different laws but forms the basis for objective evidence of your food safety HACCP system. For any food business that's been through a HACCP audit or third-party HACCP certification audit, having clear, legible food safety HACCP records can contribute to a stress-free audit process.

All HACCP certification standards including BRC, SQF, Codex HACCP, Global Gap and McDonalds require a food business to keep records. Documented food safety HACCP records provide the support and evidence that something happened.

Your records must reflect:

- Accurateness
- The entire process
- Documented deviations
- Corrective Actions
- Logs
- Forms
- Real-time data — never postpone entry or rely on memory

In the world of auditing, it is often said that "if it is not recorded or written down — it did not happen."

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STEP 13

# Validation

The plan should be validated within the first months of implementation. This serves to confirm the HACCP system is effective in controlling biological, chemical, and physical hazards.

Validation may include:

- Collecting and evaluating scientific and technical information
- Conducting validation studies
- Reviewing regulations

This will also help determine if the hazard analysis is appropriate and realistic, if it's properly controlling hazards, and if it's based on current science.

A reassessment of the HACCP plan should be reviewed annually at a minimum (or if there are any changes), and should include:

- Food safety incidents
- Rate and type of customer complaints
- Various audits
- Internal inspections
- Deviation log

To help put together your HACCP plan, use references and resources that can include:

- The latest scientific literature
- Historical and known hazards
- Relevant codes of practice
- Industry experts
- Generic models
- Food processor organizations
- Information from suppliers
- Customer requirements

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# TraceGains helps you effectively manage your HACCP plan

TraceGains' cloud-based solutions provide food and consumer-packaged goods companies with an integrated quality, supplier, compliance, and regulatory document management system that eases compliance with FSMA, GFSI, and HACCP. By automating, innovating, and streamlining Food Safety and Quality Assurance business processes, TraceGains' customers are 365 Audit Ready™ and the system typically pays for itself in as little as six months.

To help track the monitoring of your plan's objectives, TraceGains Quality Management provides the following capabilities:

**Automated Management**

Automated management of all critical control points (CCP) and prerequisite programs (PRP and oPRP).

**Centralized Platform**

An easy and centralized way to access food safety plans, workflows, and standard operating procedures (SOP).

**Monitoring**

Automated monitoring of quality components (CCPs, PRPs, and oPRPs as well as miscellaneous quality logs) to ensure each shipment has conformed with every relevant quality program.

**Training**

The system maintains a log of staff training requirements and tracks each employee's progress through each module.

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# About TraceGains

TraceGains is a supplier compliance, quality management, and NPD cloud platform that helps food, supplement, and CPG companies deliver brand promise. R&D, procurement, quality, and regulatory departments collaborate with suppliers globally on TraceGains Network to bring safe products to market faster. The system digitizes documents and information exchange and uses the data to power dashboards and reports for better business insight. Automatic alerts for regulatory issues and supply chain threats make it easy to manage risk.

TraceGains suite of software solutions provide streamlined information management with unique access to custom dashboards for Allergens, Organic, Nutrition and countless other critical documents so you can be ready for any audit at any time. What's more, TraceGains offers the ability to collect and monitor plant floor data, manage lot-by-lot compliance, and even create your own specifications. Choose the TraceGains solution that fits your business needs.

## The Power of TraceGains Network

TraceGains Network is where professionals in R&D, procurement, quality, and regulatory departments collaborate with suppliers globally to safely bring new products to market faster. Thousands of supplier locations are available to source and qualify new vendors, procure ingredients, build recipes, negotiate specifications, and automatically collect supporting documentation. On average, our customers find that 80 percent of their suppliers are already in TraceGains Network, allowing them to immediately connect and collaborate. Suppliers appreciate the ability to submit their company profile and product catalogs once and share them with the customers of their choice. With instant information sharing and visibility throughout the supply chain, TraceGains enables business growth without adding resources.

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