

Hazard Analysis and Critical Control Points (HACCP) User's Guide

Vacuum Packaging *Reduced Oxygen Packaging (ROP) Template*

Forward

The goal of this *Hazard Analysis and Critical Control Points (HACCP) User's Guide and Template* is to provide retail food operators with a basic understanding of HACCP principles and assist them in the development of their own HACCP plans. This guide is an information resource only; it is not intended to be, nor should it be used as, a standalone resource or replacement for guidance or expertise from local health departments, food safety consultants, attorneys, or process authorities. Food safety is the responsibility of the retail food operator, as set forth in local, state, and federal guidance (U.S. Food and Drug Administration Food Code § 3-502.12). All necessary measures must be taken by the retail food operator to ensure the development and enforcement of a safe and effective HACCP plan in compliance with applicable law. We hope that this user's guide will assist your facility in the development of a HACCP plan and, subsequently, maintaining compliance related to specific specialized processing methods.



The information included in this guide was compiled from a variety of resources, in particular the U.S. Food and Drug Administration's (FDA) *Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments* and Multnomah County (Oregon) Health Department's *Hazard Analysis and Critical Control Point (HACCP) Toolkit*. The development of this guide and template was made possible by a grant through the Association of Food and Drug Officials (AFDO) and the FDA.

Understanding Specialized Processes and HACCP

"Specialized processing" is a method of preparing food which have increased risk of foodborne illness. Under the rules and regulations of many health departments, specialized processes require a HACCP plan. Specialized processes include things like reduced oxygen packaging (ROP), commonly referred to as cryo-vacking, as well as acidification, fermentation, and curing.



HACCP is a proactive, scientifically proven food safety program. A HACCP plan is a prescriptive, comprehensive document that aims to ensure the safe receiving, handling, preparation, and holding of food to help ensure the delivery of a safe product to consumers. Since specialized processes create an increased risk of food borne illness, it is the responsibility of operators to prove that their process methodology will result in safe food production for the end consumer.

Glossary of Terms

Approved Source: A facility where the food is produced, prepared, or processed that meets or exceeds the standards of the responsible regulatory agencies. Approved sources are critical, as many foodborne illness investigations indicate that

the cause of foodborne illness outbreaks is often traced back to foods from unapproved sources. Each food facility must be able to demonstrate that the processors or suppliers they use are from approved sources.

Aerobic/Anaerobic: An aerobic organism, or aerobe, is an organism that can survive and grow in an oxygenated environment. In contrast, an anaerobic organism is any organism that does not require oxygen for growth.

Barrier: Anything that restrains or prevents progress. In this context, it is a hurdle or obstacle to prevent pathogen growth. Examples include temperature control, water activity levels, acidity levels, and competing organisms.

CFR: Code of Federal Regulations.

Corrective Action: An action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical Control Point (CCP): A point or procedure in a specific food process flow where loss of control may result in an unacceptable health risk.

Critical Limit (CL): The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled by critical control points to minimize the risk that the identified food safety hazard may occur.

Cross-Contamination: The transfer of harmful substances or disease-causing microorganisms to food by hands, food contact surfaces, or equipment and utensils that touch raw foods and then touch ready-to-eat foods without proper sanitation.

Data Logger (or data recorder): An electronic device that records data over time, either with a built-in instrument or sensor or via external instruments and sensors. Data loggers are often required to record temperature and humidity to ensure proper levels are not exceeded.

Deviation: Failure to meet an established critical limit for a critical control point.

FDA: United States Food and Drug Administration, which is responsible for protecting and promoting public health through the regulation of foods.

Hazard: A biological, physical, or chemical property that may cause a food to become unsafe for consumption.

pH: The symbol for the negative logarithm of the hydrogen ion concentration. In simple terms, pH is a measure of the acidity or alkalinity of a solution.

Pathogen: A microorganism (i.e. bacteria, fungi, parasite, or virus) that causes disease in humans.

Potentially Hazardous Food (PHF): A food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

Psychrotrophic: Bacteria capable of surviving or even thriving in an extremely cold environment.

Record: Documentation of monitoring observations or verification activities.

Reduced Oxygen Packaging (ROP): Commonly referred to as “cryo-vacking,” reduced oxygen packaging is when oxygen is reduced in a package by mechanically evacuating the oxygen, displacing the oxygen with another gas or combination of gases, or otherwise controlling oxygen content to a level below normal levels in the surrounding atmosphere (i.e. 21% oxygen). ROP includes:

- modified atmosphere (MAP)
- controlled atmosphere (CAP)
- cook-chill
- vacuum packaging
- sous vide

Risk: Likelihood that an adverse health event will occur within a population as a result of a food hazard.

Sanitization: The application of cumulative heat or chemicals on cleaned food contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction of representative disease microorganisms of public health importance. In simpler terms, sanitization refers to the killing of germs.

SOP: Standard operating procedure, which is a written method of controlling a practice in accordance with predetermined specifications to obtain a desired outcome. An example of a SOP would be methodically washing hands and applying gloves before touching foods to ensure that the potential of contamination is minimized.

Spore: An environmentally resistant, dormant form of certain bacterial cells that is very resistant to heat and a variety of chemical and radiation treatments that are lethal to vegetative (non-spore) cells.

TCS: A potentially hazardous food that requires time/temperature to control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

USDA: United States Department of Agriculture, which is responsible for developing and executing federal policy on farming, forestry, and food.

Validation: Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Variance: A written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of the food code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.

Vegetative Cell: A bacterial cell that is capable of actively growing. Some bacteria can transition from a vegetative cell to a spore form under the right conditions.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Water Activity (a_w): The measure of free moisture within a food item; it's the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, as indicated by the symbol “ a_w .”

Understanding Reduced Oxygen Packaging (ROP)

Reduced oxygen packaging (ROP) is a process used to package food that increases shelf life by reducing the amount of oxygen within the package. ROP can significantly slow down or prevent the growth of spoilage organisms, such as pseudomonas, yeasts, and molds. These three organisms are responsible for texture changes, odors, slime, and an off taste. Potentially hazardous foods (PHF) that are vacuum-sealed may require a HACCP plan. Most pathogenic (i.e. disease-causing) bacteria that are concerns in food are aerobic, meaning they thrive in oxygen-rich environments; however, there are two organisms of concern when conducting ROP, *Clostridium botulinum* and *Listeria monocytogenes*; *Clostridium botulinum* is an anaerobic pathogen and *Listeria monocytogenes* is a facultative anaerobe.



There are various forms of ROP. The common forms in retail food establishments include vacuum packaging, cook-chill, and sous vide. This guide is for vacuum packaging only, the process of removing air from a package of food and hermetically sealing the package so that the vacuum remains. The intent of vacuum packing is to remove air from a package of food and the package is hermetically sealed so that a vacuum remains inside the package. By removing air from around the product, the levels of oxygen in the packaging are reduced, impeding the ability of oxygen-breathing microorganisms to grow and spoil the product. The lack of oxygen also reduces the amount of spoilage due to oxidation – the process that causes apples and bananas to turn brown, for example.

HACCP Plan Development and Implementation Steps

Assembling a HACCP Team and Creating a Training Program

Special processing should not be done by just anyone in your restaurant. It's a higher risk practice, and your business is resting in the hands of the employees running your vacuum packaging operations. Therefore, you'll want to assign specific people to conduct the vacuum packaging process and ensure that you have an adequate training program that clearly outlines what the employees must know before performing this specialized process. Having a well-documented training program will help to ensure that safe food handling practices are being conducted in your kitchen. The program can be written in standard operating procedure (SOP) format, detailing each step of a particular function (e.g. how to clean the vacuum packaging machine, etc.).

You will also need to keep a training log for special processing to identify who has received training, the type of training they received, training dates, signature of the person providing the training, and signatures of employees receiving the training. This will help to ensure that:


1. The employees receive the necessary HACCP plan training.
2. The employees understand the importance of the training.
3. The employees take responsibility for doing the work correctly.
4. The employees understand what the critical limits are to reduce hazards in food and corrective actions to take in the event critical limits have not been achieved.
5. The employer provides appropriate training to ensure that the food stays safe for the customers.

 **Action Step:** Complete Table A in the *HACCP Vacuum Packaging Template*, including information for all of the HACCP Team members.


HACCP Procedural Step 1: Prerequisite Programs

Prerequisite programs or standard operating procedures are a detailed set of instructions, steps, or procedures that control the operational conditions within a food establishment to ensure that environmental conditions are favorable to the production of safe food. If you are conducting reduced oxygen packaging (ROP), the following SOPs may be required:

- No bare-hand contact with ready-to-eat foods
- Designated and segregated work area
- Cleaning and sanitizing food contact surfaces
- HACCP training procedure
- Labeling
- Continuous temperature monitoring – refrigeration data logger
- Recordkeeping
- Personal hygiene and hand washing
- Cooking potential hazardous foods
- Using and calibrating thermometers
- Employee illness policy

 **Action Step:** Go to “Procedural Step 1: Prerequisite Programs” in the *HACCP Vacuum Packaging Template* and click/select the SOPs that apply to your operation. If needed, include add other SOPs that are not listed but are pertinent to your operation. Attach all selected SOPs to your HACCP plan.

Labeling of ROP: Once packaged, vacuum packaged bags must be labeled so the packages are prominently and conspicuously shown on the principal display panels. The labeling should be in bold type on a contrasting background (see example in template). The “discard date” will be dependent on the final cooling temperature chosen and discussed in Procedural Step 4. See the example label shown in the template. NOTE: “Thaw date” refers to the date/time that the item was removed from the freezer.

 **Action Step:** Go to “Procedural Step 1: Prerequisite Programs” in the *HACCP Vacuum Packaging Template* and show an example of the actual label you will be using in your operation. Be sure it includes all required information.

HACCP Procedural Step 2: Menu Product and Recipes

It is important for staff and regulators to understand which products are covered under your HACCP plan. It is also important to consider the ingredients and processes required for the recipes since they can greatly affect the pH and water activity of the end product. It’s also important for employees to follow the recipe exactly, as changes in product preparation can impact the safety and quality of the end product.



Action Step: Complete Table B in the *HACCP Vacuum Packaging Template*. Be sure to include all menu items that will be a part of your vacuum packaging process. NOTE: You MUST attach all recipes to your HACCP plan when is submitting it to your local health department or other agency with jurisdiction. Additionally, except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a ROP method.

HACCP Procedural Step 3: Conduct a Hazard Analysis

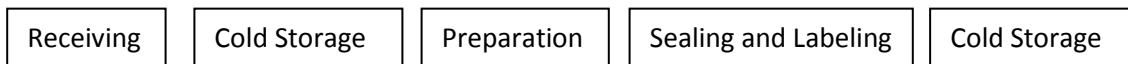
A food safety hazard, as defined below, is any unacceptable contamination by a biological, chemical, or physical agent at sufficient levels to cause a food to be unsafe for human consumption.

- **Biological Hazards:** Bacteria, bacterial toxins, viruses, and parasitic organisms that could survive, grow, or contaminate food products/raw materials and potentially cause foodborne illness.
- **Chemical Hazards:** Could result from a variety of sources, including agricultural chemicals, insecticides, fungicides, etc.; cleaning/sanitizing agents and chemicals; and misuse of food chemicals (e.g. preservatives, additives, etc.).
- **Physical Hazards:** Inadvertent field matter (e.g. stones, wood, metal fragments, etc.), inadvertent processing residues (e.g. glass, metal fragments, etc.), intentional materials (e.g. employee sabotage), and miscellaneous particulates and fragments.

A hazard analysis includes:

- Step 1: Identifying all potential biological, chemical, and physical hazards.
- Step 2: Determining whether the hazards in your facility are significant and justifying why they're hazardous.
- Step 3: Listing the control measures that can be applied to prevent the significant hazards.
- Step 4: A flow diagram of the cook-chill process operations in your facility.

A **flow diagram** documents the flow of the food product from the receiving of ingredients to the serving of the product. It's a road map to help verify that all steps for working with the food have been properly captured and analyzed for risks and hazards. Flow diagrams may look different from operation to operation and process to process. They can also help determine which steps will be identified as critical control points or may need SOPs (see Table D in the *HACCP Vacuum Packaging Template*).



Action Step: Complete Table C in the Hazard Analysis Table in the *HACCP Vacuum Packaging Template*. Check all hazards that apply, noting risks and control measures. Control measures may include things like approved source, temperature, no bare-hand contact, etc.; add or modify the table, as needed.



Action Step: Modify the Flow Diagram of Operations in the *HACCP Vacuum Packaging Template* to represent each step of your vacuum packaging process, from receiving of products to serving the product.

HACCP Procedural Step 4: Establish Control Measures in SOPs, Critical Control Points (CCPs), and Critical Limits (CL)

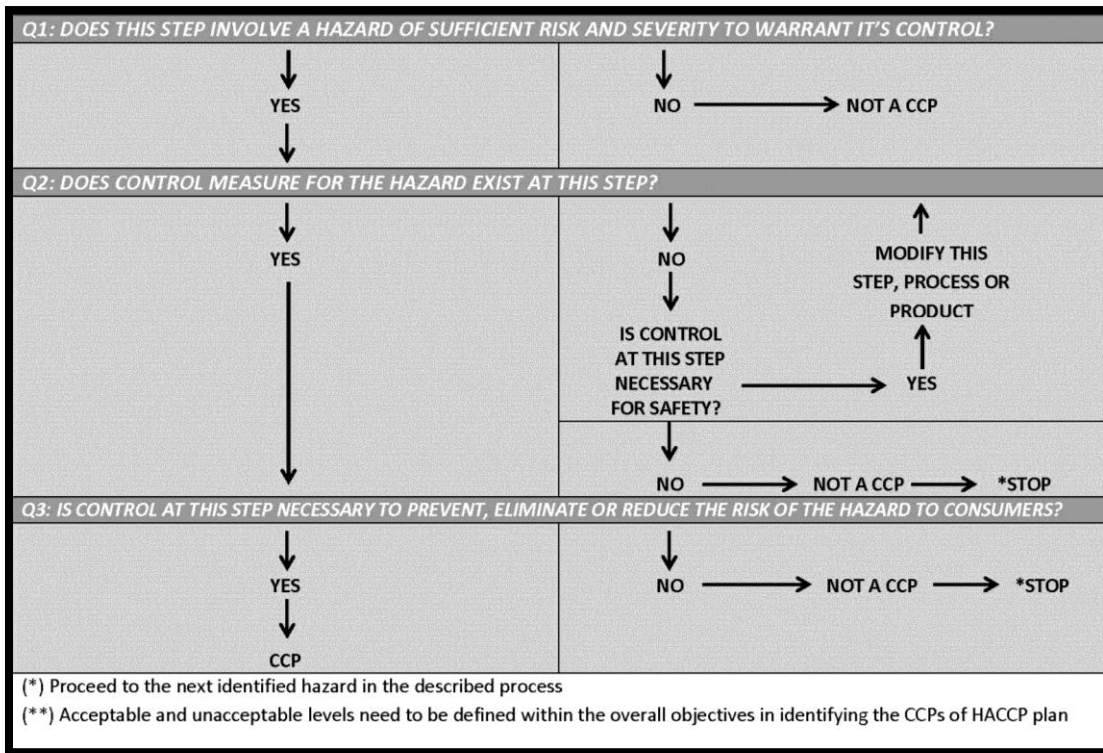
Table D in the *HACCP Vacuum Packaging Template* will be the heart of your HACCP plan; it includes hazards identified through your hazard analysis and outlines critical limits for each control measure, if the hazard can be controlled by an SOP, and if the step is considered a critical control point. The following are definitions of important terms for this step.

Step: Refers to each course of action or point within the vacuum packaging process. These steps were outlined in the flow diagram.

Hazard: Includes all physical, biological, and chemical hazards for each step of the vacuum packaging process.

Critical Control Points (CCP): Steps in the production process where a hazard is likely to occur and where a control can be applied to eliminate or effectively minimize the risk of occurrence. Use the CCP identification flow chart to help determine if a step is a critical control point.

CCP Identification Flow Chart




If an operational step is the last step at which control can be applied to prevent or eliminate a hazard or reduce it to an acceptable level, then it should be controlled as a CCP. If the hazard of concern will be controlled later in the process, then the later step will most likely be a CCP.

Not all steps are critical control points. Depending on your operation, control measures may be effectively implemented in your prerequisite programs. For instance, you may decide that sealing is best controlled through an SOP rather than through your HACCP plan. Considering the flow of food will help you make that determination.

Critical Limits (CL): Helps to maintain food safety by establishing an acceptable threshold of control for a given point in the food preparation process. Each critical control point (CCP) has a critical limit (CL). For example, to kill bacteria found in raw foods, a particular temperature must be reached for a certain length of time (e.g. bacon must be


cooked until it reaches a temperature of 145°F for at least 15 seconds; this is the required cook temperature for pork and the CCP for cooking it). Some of the most common CLs for this process should address temperature of the product when bagged, labeling, and storage limits.

 **Action Step:** Complete the “Step,” “Hazard,” “Critical Limit,” and “CCP or SOP” columns in Table D in the *HACCP Vacuum Packaging Template*, including each step of the vacuum packaging process outlined in your flow diagram in the “Step” column. For each added step, complete the columns from left to right that include hazards, controls, critical limits, and if the step is considered a CCP or can be managed by an SOP. If you will be using the cooling step, select one of the temperatures of final cooling and cold storage that you plan to use that is listed after Table D.

HACCP Procedural Step 5: Establish Monitoring Process

No process is perfect; deviations will happen. You must continually monitor hazard areas and document, in writing, when deviations in the process occur. Monitoring details (e.g. what, how, when, who) should be included in Table D of the *HACCP Vacuum Packaging Template*, as monitoring can help to:

- Keep track of processes and identify problems early.
- Alert you if a CCP is not staying within its critical limit.
- Document processes/issues for future reference.

 **Action Step:** Complete the “Monitor” column in Table D of the *HACCP Vacuum Packaging Template* for each critical control and SOP. For “Who,” list position names (e.g. manager or sous chef) instead of employee names since staffing does change.

HACCP Procedural Step 6: Develop Corrective Actions

The person most familiar with the HACCP plan should manage and correct critical limit control problems. This person must:


- Identify what is causing the problem and correct it.
- Determine proper action to be taken with the affected food product.
- Document the action taken to correct the problem.

In the HACCP plan, the corrective actions should:

- Explain what happens when a deviation occurs.
- Identify who will handle deviations and corrective actions.
- Provide a written record of the corrective actions taken.

When a critical limit is not met, a corrective action must be carried out immediately. Common corrective actions may include but are not limited to:

- Continue to cook food to proper temperature.
- Reheat food.
- Discard food.
- Reject food.

 **Action Step:** Complete the “Corrective Actions” column for each step in Table D in the *HACCP Vacuum Packaging Template*.

HACCP Procedural Step 7: Ongoing Verification Plan

Verification procedures are activities other than monitoring that ensure that your HACCP plan is effective and functioning properly so that your process remains safe. These activities include review of the initial plan, periodic maintenance of the plan, and verification of regular documentation.



Action Step: Complete the “Verification Activities” column for each step in Table D in the *HACCP Vacuum Packaging Template*. Add or subtract activities, as appropriate, for your program, listed in the Procedural Step 7: Ongoing Verification Plan section in the *HACCP Vacuum Packaging Template*.

HACCP Procedural Step 8: Recordkeeping

Documentation of your processes does not need to be complex, but it must be effective. Records must be kept onsite and easily produced if an environmental health specialist requests to review them. Examples of documentation that are required to be used in the HACCP plan include:

- SOPs/prerequisite programs
- Training logs
- Recipes
- Monitoring records
- Corrective action logs
- Verification and validation records
- Calibration logs
- pH, a_w testing, lab tests
- Temperature logs
- Cooling logs
- Reheating logs
- Shellfish tags
- Equipment maintenance records
- Pest control records



Action Step: Complete Table E in the *HACCP Vacuum Packaging Template*.

More Information

- U.S. Food and Drug Administration: *Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments*. <https://www.fda.gov/downloads/Food/GuidanceRegulation/HACCP/UCM077957.pdf>
- Multnomah County Health Department Hazard Analysis and Critical Control Point (HACCP) Toolkit. <https://multco.us/file/39943/download>

Notes

- Technical information for this project was reviewed by: George M. Nakamura, R.E.H.S., D.A.A.S., M.P.A., FSSME and the FDA.
- Special thanks to Chef, Greg Biggers and the Sofitel Chicago
- Check with your regulatory agency for special requirements that may be related to the vacuum packaging of cheese, foods with high levels competing organisms such as raw meat, fish and poultry or raw vegetables and cured meats.