



Public Health

Consumer Protection Program

Date

Dear Facility Name

Thank you for your interest in developing a Hazard Analysis Critical Control Point (HACCP) plan. When you have compiled your completed HACCP plan with all required information, **please submit the plan in its entirety** to Boulder County Public Health. The fee for review of the HACCP plan is \$400. Fees are due at the time the HACCP plan is submitted.

Required Materials

- ☐ Hazard analysis description/process
- ☐ HACCP Team members/roles
- ☐ Food flows –critical control points(CCP), critical limits and corrective actions
- ☐ Labeling, shelf life information, date marking
- ☐ Monitoring devices and frequency, including information about continuous temperature monitoring devices
- ☐ Product testing (when required)
- ☐ Equipment information (must be commercial)
- ☐ Standard Recipes
- ☐ Recordkeeping/location
- ☐ Employee training procedures
- ☐ Supporting documents or standard operating procedures (SOPs):
 - ☐ Bare-hand contact on ready-to-eat (RTE) foods
 - ☐ Cross-contamination
 - ☐ Employee illness policy
 - ☐ Logs (cooling, reheat)
 - ☐ Cleaning and sanitizing
 - ☐ Thermometer calibration
 - ☐ pH calibration (when applicable)
- ☐ Approval letter from Process Authority (required for Specialized Processes)
- ☐ Better Process Control School certification for those intending to acidify products for shelf stability

Specific information about HACCP requirements is available in the Colorado Retail Food Rules and Regulations, Section 3-606; 607, *Modified Atmosphere Packaging* and the Colorado Food Act, 25-4-1605, *Statement of Required HACCP plan submission*. A detailed HACCP guide is available at www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/UCM077957.pdf

For more information about HACCP plans, please review the attached information, or contact our office at 303-441-1564.

Sincerely,

Lane Drager,
Consumer Protection Program Coordinator



Hazard Analysis Critical Control Point (HACCP) Plan

Creating a Plan

Preliminary Steps

1. **Assemble an HACCP team**, including one person who is trained in HACCP principles. Although this may seem like a daunting task, especially for a very small or family-centered company, it is best to have more than one person working on the development of HACCP system(s). HACCP is an overall process control system and it takes a variety of knowledge and experience to create a good system. If your company has only a few people in it, they may all need to be on the HACCP team.
2. **Identify and document common prerequisite programs** (standard operating procedures; SOPs) you already have in place. Examples of SOPs include:
 - How to make sure that your suppliers are safe
 - Policy about using commercial production equipment, including established and documented maintenance and calibration schedules
 - Cleaning and sanitation schedules with established and documented procedures
 - Personal hygiene procedures
 - Staff training procedures
 - Chemical control plan
 - Pest control plan
 - How items will be handled and screened upon receipt from shippers/suppliers, including documented procedures and storing shipping logs and order receipts
3. **Describe the food and its method of production and distribution**; identify the intended use and the intended consumers of the food products. This must include every step in the food production process. Use these questions to help ensure that all of the key information in the food production process is included.
 - Do I have a standard recipe?
 - What is the common name of the product?
 - How is the product to be used?
 - What type of packaging encloses the product?
 - What is the length of shelf life of each product, and at what temperature?
 - Where will the product be sold?
 - Who is the intended consumer of the product?
 - What is the intended use?
 - What labeling instructions are needed?
 - Is special distribution control needed?
4. **Develop and verify process flow diagram**. A flow diagram is a picture of a process. The diagram does not to be created on a computer, but it does needs to be an accurate, clear sketch of the process used in your facility to make the product. An example flow diagram might include, but is not limited to, the following steps:
 - Receiving of ingredients
 - Thawing
 - Marinating
 - Grinding/mixing/blending
 - Cooking procedure
 - Cooling procedures/freezing
 - Packaging
 - Storing
 - Distributing
 - Reheating

- Serving

Documenting the Seven Principles

Each of the following seven HACCP principles must be developed and documented within the HACCP plan.

Principle 1: Conduct a hazard analysis.

A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. A hazard analysis is designed to question the effect of factors on the safety of the food. Ask the following questions, as appropriate, to each step in the flow diagram.

1. Ingredients

- Does the food contain any sensitive ingredients that are likely to create microbiological hazards (e.g. salmonella, staphylococcus aureus), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues), or physical hazards (stones, glass, bone, metal)?

2. Intrinsic factors of food. This includes the physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrates, water activity, preservatives) of the food, during and after preparation, that can cause or prevent a hazard.

- Which intrinsic factors of the food must be controlled in order to ensure food safety?
- Does the food permit survival or multiplication of pathogens and/or toxin formation before or during preparation?
- Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?
- Are there other similar products in the market place? What has been the safety record for these products?

3. Preparation/processing procedures

- Does the preparation procedure or process include a control step that destroys pathogens or their toxins? Consider both vegetative cells and spores.
- Can the product be contaminated between the preparation step (e.g., cooking) and packaging step?

4. Microbial content of the food

- Is the food commercially sterile (e.g., low acid, canned food)?
- Is it likely that the food will contain viable spore-forming or non-spore-forming pathogens?
- What is the normal microbial content of the food stored under proper conditions?
- Does the microbial population change during the time the food is stored before consumption? Does that change in microbial population alter the safety of the food?

5. Facility design

- Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?
- Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
- Is the traffic pattern for people and moving equipment a potential source of contamination?

6. Equipment design

- Will the equipment provide the time/temperature control that is necessary to meet critical limits?
- Is the equipment properly sized for the volume of food that will be prepared?
- Can the equipment be controlled so that the variation in performance will be within the tolerances required to produce a safe food?
- Is the equipment reliable, or is it prone to frequent breakdowns?
- Is the equipment designed so that it can be cleaned and sanitized?
- Is product contamination with hazardous substances (e.g., glass) likely to occur?
- What product safety devices such as time/temperature integrators are used to enhance consumer safety?

- Will the product be held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice per day?

7. Packaging

- Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
- Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?
- Is the package clearly labeled “Keep Refrigerated” if this is required for safety?
- Does the package include instructions for the safe handling and preparation of the food by the consumer (if applicable)?
- Are tamper-evident packaging features used?
- Is each package legibly and accurately coded to indicate production lot?
- Does each package contain the proper label?

8. Sanitation

- Can the sanitation practices that are employed impact the safety of the food being prepared?
- Can the facility be cleaned and sanitized to permit the safe handling of foods?
- Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

9. Employee health, hygiene, and education

- Can employee health or personal hygiene practices impact the safety of the food being prepared?
- Do the employees understand the food preparation process and the factors they must control to ensure safe foods?
- Will the employees inform management of a problem which could impact food safety?

10. Conditions of storage between packaging and the consumer (when applicable)

- What is the likelihood that the food will be improperly stored at the wrong temperature?
- Would storage at improper temperature lead to a microbiologically unsafe food?

11. Intended use

- Will the food be heated by the consumer? Will there likely be leftovers?

12. Intended consumer

- Is the food intended for a population that does not have an increased risk of becoming ill?
- Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm and immunocompromised individuals)?
- Is the product to be consumed on site at the facility or at the consumer’s home?

Principle 2: Identify critical control points.

A critical control point (CCP) is a point, step, or procedure in a food process at which control can be applied, and as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

Principle 3: Establish critical limits for each critical control point.

A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point in order to prevent, eliminate, or reduce the hazard to an acceptable level.

Principle 4: Establish critical control point monitoring requirements.

Monitoring activities ensure that the process is under control at each critical control point. Each monitoring procedure and its frequency must be listed in the HACCP plan.

Principle 5: Establish corrective actions.

Corrective actions are the actions to be taken when the monitoring activity shows that there was deviation from an established critical limit. The HACCP plan must identify the corrective actions to be taken if a critical limit is not met so no hazardous food is served to consumers.

Principle 6: Establish record-keeping procedures.

All facilities must maintain a hazard analysis and written HACCP plan, including records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations. These records must be kept on-site and available for inspection. Indicate in your plan where these records will be located.

Principle 7: Establish procedures for verifying the HACCP system is working as intended.

Verification ensures that the plans do what they were designed to do; that is, ensuring the production of safe product. Verification may include procedures such as review of HACCP plans, CCP records, critical limits, and microbial sampling and analysis. The HACCP plan must include verification tasks to be performed by personnel, including microbial testing, where needed. Facilities must validate their own HACCP plans.

Records to Keep with HACCP Plan

Ingredients

- Records from all monitored CCPs.
- Supplier certification documenting compliance with establishment's specifications.
- Establishment's audit records verifying supplier compliance.
- Storage temperature record for temperature-sensitive ingredients.

Preparation

- Records from all monitored CCPs.
- Records verifying the continued adequacy of the food preparation procedures.

Packaging

- Records indicating compliance with specifications for packaging materials.
- Records indicating compliance with sealing specifications.

Finished product

- Sufficient data and records to establish the efficacy of barriers in maintaining product safety.
- Sufficient data and records to establish the safe shelf-life of the product if age of product can affect safety.
- Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

Storage and distribution

- Continuous temperature records.
- Records that show no products were used after the shelf-life date on temperature-sensitive products.

Deviation and corrective action

- Records of all actions taken following deviations at a CCP.
- Reassessment records and modifications to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

Employee training

- Records indicating that employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures.

BCPH HACCP Submittal Form

Please submit this cover sheet with your HACCP plans

Please select the option that best applies to you

I am applying for a HACCP plan review of the following Process (may chose more than one):

_____ Sous Vide
_____ Cook Chill
_____ Vacuum Packaging
_____ Other (please describe) _____

Name of Facility: _____

Address: _____ Suite / Unit #: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax _____

Email: _____

Name of Owner: _____

Name of Principle Contact Person for this process: _____

Address: _____ Suite / Unit #: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax _____ Email: _____

Fee Collected (\$400)

Paid in Full _____ Check # _____ Other _____

Consulting or 3rd party contact info (such as Process Authority)

For Internal Use Only

Date Submitted: _____ Received by _____

Staff assigned to _____ Date Assigned _____

Other Notes: