



**MASSACHUSETTS**  
ENVIRONMENTAL HEALTH  
ASSOCIATION



# Reviewing a HACCP Plan

**Reduced Oxygen Packaging (ROP)**  
*Without A Variance*

**Cook-Chill - Pulled BBQ Chicken**

*Presenter*

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# Background

- During the past decade, retail food establishments have expanded their operations to include food processing-type operations, such as reduced oxygen packaging, acidification, fermentation, smoking, curing, and drying, often using sophisticated technologies and equipment. **These specialized processes present a significant health risk if not conducted under strict operational procedures.**
- For this reason, if a retail establishment conducts a specialized process, they must provide a HACCP plan to the health department for approval before beginning that operation.

- For jurisdictions that have adopted The Food Code and/or additional requirements, regulators are responsible for ensuring that HACCP plans are valid prior to approving them to ensure that they will eliminate or significantly reduce identified hazards that may contribute to foodborne illness.

## **Today's Goal:**

Review a sample HACCP plan so you can see how all the pieces fit together.

# Primary Resource

Regulatory information is based primarily on the U.S. Public Health Service 2013 FDA Food Code with 2015 Amendments (hereinafter referred to as The Food Code) and supplemental MA regulations *105 CMR 590.000: State Sanitary Code Chapter X: Sanitation Standards for Food Establishments*, therefore regulators may need to modify information based on their jurisdictional requirements.

## **Applicable Regulations for Specialized Processes or Operations Requiring a HACCP Plan**

- § 8-201.13 When a HACCP Plan is Required
- § 8-201.14 Contents of a HACCP Plan
- § 8-103.12 Conformance with Approved Procedures

**Regulation: § 8-201.13 When a HACCP Plan is Required**

- A) Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under § 8-201.14 and the relevant provisions of this Code if:
1. Submission of a HACCP plan is required according to law;
  2. A variance is required as specified under § 3-502.11, ¶ 4-204.110(B), or Subparagraph 3-401.11(D)(3); or
  3. The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under § 8-201.12, an inspectional finding, or a variance request
- B) A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under § 3-502.12.

## Regulation: § 8-201.14 Contents of a HACCP Plan

For a food establishment that is required under § 8-201.13 to have a HACCP plan, the plan and specifications shall indicate:

- A) A categorization of the types of TCS food(s) that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority;
- B) A flow diagram by specific food or category type identifying critical control points and providing information on the following:
  - 1. Ingredients, materials, and equipment used in the preparation of that food, and
  - 2. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
- C) Food employee supervisory training plan that addresses the food safety issues of concern;
- D) A statement of standard operating procedures for the plan under consideration including clearly identifying:
  - 1. Each Critical Control Point (CCP),
  - 2. The Critical Limits for each CCP,
  - 3. The method and frequency for monitoring and controlling each CCP by the food employee designated by the person-in-charge (PIC),
  - 4. The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCPs,
  - 5. Action to be taken by the PIC if the critical limits for each CCP are not met, and
  - 6. Records to be maintained by the PIC to demonstrate that the HACCP plan is properly operated and managed; and
- E) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

**Regulation: § 8-103.12 Conformance with Approved Procedures**

If the regulatory authority grants a variance as specified in § 8-103.10, or a HACCP plan is otherwise required as specified under § 8-201.13, the permit holder shall:

- A) Comply with the HACCP plans and procedures that are submitted as specified under § 8-201.14 and approved as a basis for the modification or waiver; and
  
- B) Maintain and provide to the regulatory authority, upon request, records specified under §§ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;
  - 1. Procedures for monitoring critical control points,
  - 2. Monitoring of the critical control points,
  - 3. Verification of the effectiveness of an operation or process, and
  - 4. Necessary corrective actions if there is failure at a critical control point

## § 3-502.12

### Reduced Oxygen Packaging Without a Variance, Criteria

## Request Letter

As required by ¶ 8-201.13 (B) of the 2013 FDA Food Code, we are submitting a HACCP plan, requesting approval to vacuum package cooked, pulled BBQ chicken using a cook-chill process as outlined in ¶ 3-502.12 (D) which allows foods to be vacuum packaged, without a secondary barrier, using time-temperature combinations that provide equivalent food safety protection to control the growth and toxin formation of *C. botulinum* and the growth of *Listeria monocytogenes* without the need for a variance provided that an approved HACCP plan is in place.

The information required by relevant sections of the Food Code, as shown on the following pages, has been incorporated into our HACCP plan. We have also developed and implemented comprehensive SSOPs that are essential to ensuring that food is not being compromised before or after the vacuum packaging process. We will keep the HACCP plan, SSOPs, and relevant records in a binder for review during inspections.

## § 3-502.12

# Reduced Oxygen Packaging Without a Variance, **Criteria**

### *Cook-Chill*

(D) A food establishment that packages food using a cook-chill process shall:

- (1) Provide to the regulatory authority (RA) prior to implementation, a HACCP Plan that contains the information as specified under ¶¶ 8-201.14 (B) and (D) (*see below*);

### ¶ 8-201.14 (B)

- (A) A categorization of the types of TCS food(s) that are specified in the menu such as soups, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority;
- (B) A flow diagram by specific food or category type identifying critical control points (CCPs) and providing information on the following:
  - (1) Ingredients, material, and equipment used in the preparation of that food, and
  - (2) Formulation or recipes that delineate methods and procedural control measures that address the food safety concerns involved;

## ¶ 8-201.14 (D)

A statement of standard operating procedures for the plan under consideration including clearly identifying:

1. Each CCP,
2. The critical limits for each CCP,
3. The method and frequency for monitoring and controlling each CCP by the food employee designated by the person in charge,
4. The method and frequency for the Person in Charge (PIC) to routinely verify that the food employee is following standard operating procedures and monitoring CCPs,
5. Action to be taken by the person in charge if the critical limits for each CCP are not met, and
6. Records to be maintained by the person in charge to demonstrate that the HACCP Plan is properly operated and managed

(2) Ensure the FOOD is:

(a) Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer;

(b) Cooked to heat all parts of the food to a temperature and for a time as specified under ¶¶ 3-401.11 (A), (B), and (C),

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,

(d) Placed in a package with an oxygen barrier and immediately after cooking and before reaching a temperature below 135°F,

(e) Cooled to 41°F in the sealed package or bag as specified under § 3-501.14 and subsequently:

(i) Cooled to 34°F within 48 hours of reaching 41°F and held at that temperature until consumed or discarded within 30 days after the date of packaging; **We have chosen this option**

(ii) Cooled to 34°F within 48 hours of reaching 41°F, removed from refrigeration equipment that maintains a 34°F food temperature and then held at 41°F or less for no more than 72 hours, at which time the food must be consumed or discarded;

(iii) Cooled to 38°F or less within 24 hours of reaching 41°F and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded; or

(iv) Held frozen with no shelf-life restriction while frozen until consumed or used.

- (f) 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 daily,
  - (g) Labeled with the product name and the date packaged; and
- (3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan and:
- (a) Make such records available to the regulatory authority upon request, and
  - (b) Hold such records for at least 6 months; and

(4) Implement written operational procedures as specified under Subparagraphs **(B)(5)** and **(B)(6)** of this section.

Includes operational procedures that:

- (a) Prohibit contacting food with bare hands,
- (b) Identify a designated area and the method by which:
  - (i) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and
  - (ii) Access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation, and
- (c) Delineates cleaning and sanitization procedures for food-contact surfaces; and

**Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:**

- (a) Concepts required for a safe operation,**
- (b) Equipment and facilities, and**
- (c) Procedures specified under subparagraph (B)(5) of this section and ¶¶ 8-201.14 (B) and (D).**

**Model Hazard Analysis Critical Control Point (HACCP) Plan Review Application**

Establishment Name:	Tel:
Address:	Fax:
Owner/ Person-in-Charge	E-mail:
HACCP Plan Contact:	Tel:

**Please note that prerequisites for plan approval are 1) compliance with 105 CMR 590.000 and 2) the implementation for effective standard operating procedures (SOPs) for:**

- Food Protection Management
- Employee Health and Hygiene
- Time/Temperature Controls
- Cleaning and Sanitizing
- Approved Food Sources
- Protection From Contamination
- Protection From Chemicals
- Facilities/Equip. Design & Maint.

**Please review/use this checklist to verify that you have included the following in your plan:**

- Purpose of Submission (i.e. Variance or Code Requirement - Include Code Preference)
- Name of food product and process for which the plan is being submitted
  - Include formulation of ingredients, if required
  - Include facility layout, if required
  - Include copy of labeling, if required
- A flow chart, showing how the product flows through the establishment, including an accurate description of how the food is prepared, held, served, transported etc.
- Identification of each Critical Control Point (CCP) in the process.

For Each CCP

- A description of the hazard(s)
- A description of monitoring procedure(s) and a sample of form(s) that will be used to document the monitoring activities
- A description of verification procedure(s) and sample of form(s) that will be used to document the verification activities by PIC
- A description of plan verification and validation procedure(s) (example: annual review, scientific data, modand sample of form(s) that will be used to document the verification activities by PIC)
- A statement that an update, signed copy of the plan will be maintained on the premises for review by the regulatory authority.
  - Name of the person responsible for administering and updating the plan.
  - A statement that the regulatory authority will be informed of any significant changes in the process that may affect the accuracy or effectiveness of the plan prior to implementation, and
  - A statement that updated plans will be submitted to the regulatory authority, upon request.
  - Laboratory data, if required
- Employee training plan and sample form(s) that will be used to document employee training

**All of the information submitted is accurate to the best of my knowledge. All violations noted during previous food safety inspections have been corrected and the operation is in compliance with 105 CMR 590.000 Minimum Sanitation Standards for Food Establishments - Chapter X**

I understand that failing to comply with this plan and/or falsification of monitoring, corrective action, or verification records may result in a suspension of operations in accordance with 105 CMR 590.010 (§ 8-103.12).

\_\_\_\_\_

**Permit Holder or Person-in-Charge** \_\_\_\_\_

**Signature/Title Date** \_\_\_\_\_

Date	Reviewer	Comments	Accepted

**Implementation Date:**

**Principle # 1 of HACCP - Hazard Analysis and Flow Chart**

The documents written to support Principle #1 of HACCP are some of the most critical and demanding documents in the written plan. Under Principle #1, the following need to be included in a logical order:

- Name of the food product and the special process for which the HACCP plan is being submitted.
- Is a variance petition included? Is sufficient data provided to support the petition?
- Detailed formulation and complete list of ingredients.
- Packaging and food contact materials, if used. Show that all are approved for food use. Is package ROP?
- Facility layout and information on whether a dedicated workspace is provided to conduct the special process.
- Copy of labeling – Check for any required warning concerning temperatures or shelf-life and disposal of food.
- Hazard analysis.
- Intended use of product/institutional use/HSP?
- How it will be sold or served, including package size.
- Shelf-life.
- A detailed flow chart showing the holding and preparation of the food product from receiving raw ingredients through packaging and any subsequent distribution. Flow chart should include each specific step and should include cooking, filling and specific temperatures, times, pH or other hurdles that are designed to control food hazards.

**Principle #2 of HACCP – Establish Critical Control Points**

**The following should be provided for you to review:**

- A description of the pertinent hazards associated with this food and special process.
- Critical control points on the flow chart that are designed to control hazards associated with the food.
- Description of how the CCP will control the pertinent hazards and specific reference information source.

**Principle #3 of HACCP – Establish Critical Limits**

**A CL must be provided for each CC.**

- Is the critical limit correct based on Food Code?
- Can the CL be measured? How?
- Will this CL control the hazard(s)?

**Principle #4 of HACCP – Establish Monitoring Procedures**

**The following should be provided.**

- List of items to be monitored. The list will vary somewhat depending upon the special process.
- Forms or checklists used for monitoring each item.
- Who will monitor the item? When will it be monitored and how often?
- Examples of items that might be monitored: sanitation, pH, aw, calibration of equipment, temperatures, recipe (each batch), corrective actions, employee training, plan verification and review, HACCP revisions - changes in the recipe or protocols, receiving, food disposal, other.
- Indicate if monitoring is an OBSERVATION or a MEASUREMENT.
- Is instrument calibrated?
- Is employee training documented?
- How will records for continuous monitoring be provided? (example: cook chill/drying meat/fermenting).

**Principle #5 of HACCP – Establish Corrective Actions**

**The following should be provided:**

- Have a specific corrective action for each CCP that is out of compliance.
- Who will be responsible for the corrective action?
- How will each occurrence be documented?
- Plan for food disposal when necessary (SOP).
- Does the established monitoring plan identify all deviations?

**Principle #6 of HACCP – Establish Record Keeping Procedures**

**The following should be provided:**

- Where are records?
- How long will records be kept?
- Specify records to be kept.
- Plan revision schedule.
- Where are SOP and SSOP Records? Employee training records, monitoring records location?

**Principle #7 of HACCP – Establish Verification Procedures**

**The following should be provided:**

- WHO is responsible for verification?
- What is the procedure for verification and the frequency?
- What will be verified? Will records also be verified?
- Will the verification confirm that established procedures are followed?
- Will the verification be documented in writing and any actions taken recorded?
- Is the HACCP system reviewed annually to keep information up-to-date?

Model HACCP Field Verification Report Form		
Establishment Name:		
Address:		
Person-in-Charge		
Date Written Plan Validated		
Food Product and Process		
<b>Validated Plan</b>	<b>In</b>	<b>Out</b>
HACCP plan validated by the regulatory authority available for review		
<b>Prerequisites</b>	<b>In</b>	<b>Out</b>
Establishment has implemented effective standard operating procedures and is in compliance with 105 CMR 590.000 (Document violations on Food Establishment Inspection Report Form)		
<b>Accurate Description of Product/Process and Intended Use</b>	<b>In</b>	<b>Out</b>
Food flow is consistent with flow chart (attached)		
<b>Hazard(s)</b>	<b>Critical Control Point(s)</b>	<b>Preventative Measure(s) / Critical Limit(s)</b>
<b>Monitoring Procedures</b>	<b>In</b>	<b>Out</b>
<b>Food Employee Knowledge of Corrective Actions if Critical Limit(s) Exceeded or Not Met for each CCP</b>	<b>In</b>	<b>Out</b>
<b>Verification Process</b>	<b>In</b>	<b>Out</b>

# Resources

# Field Verification Checklists

FIELD REFERENCE GUIDE

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## Special Processes at Retail

The Center for  
Agriculture and  
Food Security  
and Preparedness



THE UNIVERSITY of TENNESSEE **UT**  
KNOXVILLE  
COLLEGE OF VETERINARY MEDICINE



**MASSACHUSETTS**  
ENVIRONMENTAL HEALTH  
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# A REGULATOR'S GUIDE:

## Validation and Verification Of HACCP Plans In Retail Food Establishments

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