

Janet T. Mills  
Governor

Sara Gagné-Holmes  
Commissioner



Maine Department of Health and Human Services  
Maine Center for Disease Control and Prevention  
11 State House Station  
286 Water Street  
Augusta, Maine 04333-0011  
Tel; (207) 287-8016; Fax (207) 287-2887  
TTY: Dial 711 (Maine Relay)

## **Maine Health Inspection Program's HACCP & Variance Guidance and Resources**

### **Table of contents**

- I. Purpose
- II. Definitions
- III. Pertinent Code Sections
- IV. 2013 Maine Food Code HACCP/Variance Requirements Table
- V. HACCP Plan contents
- VI. Variance requirements and Process
- VII. Links to Contact information for UMO, DACF, USDA, and food safety consultants.

### **I. Purpose**

The purpose of this guidance document is to answer frequently asked questions about HACCP plans and variances and to gather the best publicly available information in one place.

The audience is both the public, licensees, and the Health Inspectors tasked with educating and regulating these operations.

## II. Definitions

**Clostridium Botulinum** is a Gram-positive, rod-shaped, spore-forming bacterium. It is an obligate anaerobe; the organism survives in an environment that lacks oxygen. *C. botulinum* can produce a neurotoxin only during sporulation, which can happen only in an anaerobic environment. Botulinum toxin can cause botulism and is the most potent toxin known to science, natural or synthetic.

**Cook Chill** is when cooked Food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged Food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

**Critical Control Point** is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Curing** means the addition of salt, sugar, nitrites, or nitrates for the purposes of preservation, color development, or flavor. The use of nitrites, nitrates, and/or curing for preservation requires a variance.

**Eating Establishment** means any place where food or drink is prepared and served or served to the public for consumption on the premises or prepared and served or served ready to eat to the public for consumption off the premises. "Eating establishment" includes places in the entertainment, hospitality, recreation, restaurant, and tourism industries; catering establishments; correctional facilities; hospital cafeterias; mobile eating places; public and private schools; retail frozen dairy product establishments; and workplace eating establishments and places where food is prepared for vending machines dispensing food other than in original sealed packages. "Eating establishment" does not include:

- A. A place preparing and serving food that is licensed pursuant to state law by a state agency other than the department as long the licensing of the place includes regular food safety inspections;
- B. A place serving food only to residents, such as a boarding home, a retirement home, or an independent living place; and
- C. A farm stand that offers only whole, uncut fresh fruits and vegetables.

**Food Establishment** means a factory, plant, warehouse or store in which food and food products are manufactured, processed, packed, held for introduction into commerce or sold. "Food establishment" includes a caregiver, as defined in section 2422, subsection 8-A, and a registered dispensary, as defined in section 2422, subsection 6, that prepare food containing cannabis for medical use by a qualifying patient pursuant to chapter 558-C.

**HACCP** is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product.

**HIP** means the Health Inspection Program of the Department of Health and Human Services. The HIP is the primary license entity for Eating Establishments.

**Listeria Monocytogenes** is the species of pathogenic bacteria that causes the infection listeriosis. It is a facultative anaerobic bacterium, capable of surviving in the presence or absence of oxygen. Listeriosis ranks third in total number of deaths among foodborne bacterial pathogens, with fatality rates exceeding even *Salmonella* spp. and *Clostridium botulinum*.

**ROP** is reduction of the amount of oxygen in a Package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere, (approximately 21% at sea level); and involves a Food for which the hazards *Clostridium botulinum* and *Listeria monocytogenes* require control in the final Packaged form.

**Smoking** is the process of flavoring, browning, cooking, or preserving food by exposing it to smoke from burning or smoldering material, most often wood. Only smoking as a method of food preservation requires a variance.

**Sous Vide** is a process in which raw or partially cooked Food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

**Variance** means a written document issued by the Regulatory Authority that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the Regulatory Authority, a health Hazard or nuisance will not result from the modification or waiver.

### III. Pertinent Code Sections

#### 3-502.11 Variance Requirement

A Food or Eating Establishment shall obtain a Variance from the Regulatory Authority, as specified in §8-103.10 and under §8-103.11 before:

(A) **Smoking Food** as a method of Food preservation rather than as a method of flavor enhancement;

(B) **Curing Food**;

(C) Using **Food Additives or adding components** such as vinegar:

(1) As a method of Food preservation rather than as a method of flavor enhancement, or

(2) To render a Food so that it is not Potentially Hazardous Food (Time/Temperature Control for Safety Food);

(D) Packaging Food using a **Reduced Oxygen Packaging** method, except where the growth of, and toxin formation by Clostridium botulinum; and the growth of Listeria monocytogenes are controlled as specified under §3-502.12.

(E) Operating a **Molluscan Shellfish life-support system display tank** used to store or display shellfish that are offered for human consumption;

(F) **Custom processing animals that are for personal use** as Food and not for sale or service in a Food or Eating Establishment;

(G) Preparing Food by **another method** that is determined by the Regulatory Authority to require a Variance; or

(H) **Sprouting seeds or beans.**

#### **3-502.12 Reduced Oxygen Packaging, Criteria.**

*(with updated allowances due to newer versions of the FDA Food Code)*

(A) **Except for a Food or Eating Establishment that obtains a Variance** as specified under §3-502.11, a Food or Eating Establishment that packages Potentially Hazardous Food (Time/Temperature Control for Safety Food) using a Reduced Oxygen Packaging method shall control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes. *(A HACCP plan is not required for foods placed in ROP and subsequently removed from ROP within 48 hours provided these foods are labeled with the production date and time and held at 41 F or lower during storage. This exemption only applies to foods that can be placed in ROP without a variance.)*

(B) A Food or Eating Establishment that **packages Potentially Hazardous Food** (Time/Temperature Control for Safety Food) **using a Reduced Oxygen Packaging method shall have a HACCP Plan** that contains the information specified under 8-201.14(D) and that:

- (1) Identifies the Food to be Packaged;
- (2) Except as specified under (C) - (E) of this section, requires that the Packaged Food shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria:
  - (a) Has an AW of 0.91 or less,
  - (b) Has a PH of 4.6 or less,
  - (c) Is a Meat or Poultry product cured at a Food Processing Plant regulated by the USDA using substances specified in 9 CFR 424.21, (Use of food ingredients and sources of radiation)(2012 ed.), and is received in an intact Package, or
  - (d) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;
- (3) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
  - (a) Maintain the Food at 5°C (41° F) or below, and
  - (b) Discard the Food if within **30** calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;
- (4) Limits the shelf life to no more than **30 days at 41°F without a variance** from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
- (5) Includes operational procedures that:
  - (a) Prohibit contacting Ready-to-Eat Food with bare hands, as specified under 3-301.11(B),
  - (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) Delineate cleaning and Sanitization procedures for Food-Contact Surfaces; and
- (6) 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(D).

(C) Except for **Fish that is frozen before, during, and after packaging**, a Food or Eating Establishment may not package Fish using a Reduced Oxygen Packaging method.

(D) Except as specified under (C) of this section, a Food or Eating Establishment that **packages Food using a cook-chill or sous vide process** shall:

- (1) Implement a HACCP Plan that contains the information as specified under 8-201.14(D);
- (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,
  - (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 sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 57°C (135°F),
  - (e) Cooled to 5°C (41°F) in the sealed package or bag, as specified under § 3- 501.14, and subsequently:
    - (i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of packaging;
    - (ii) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the Food must be consumed or discarded;
    - (iii) Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (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.
    - (v) Cook chill and sous vide foods may be held for 7 days at 41F after cooling to 41F*
  - (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) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and
  - (h) 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 Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.

- (E) A Food Establishment that **packages cheese using a Reduced Oxygen Packaging** method shall:
- (1) Limit the cheeses packaged to those that are (1) commercially manufactured in a Food Processing Plant; (2) with no ingredients added in the Food Establishment; and
  - (3) that meet the Standards of Identity as specified in 21 CFR 133.150 (Hard cheeses)(2012 ed.), 21 CFR 133.169 (Pasteurized process cheese)(2012 ed.) or 21 CFR 133.187 (Semisoft cheeses)(2012 ed.);

- (2) Have a HACCP Plan that contains the information specified under 8-201.14(D) and as specified under (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;
- (3) Labels the package on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and
- (4) Discards the Reduced Oxygen Packaged cheese, if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

### **8-103.11 Documentation of Proposed Variance and Justification.**

Before a Variance from a requirement of this Code is Approved, the information that shall be provided by the Person requesting the Variance and retained in the Regulatory Authority's file on the Food or Eating Establishment includes:

- (A) A statement of the proposed Variance of the Code requirement citing relevant Code section numbers;
- (B) An analysis of the rationale for how the potential public health Hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and
- (C) A HACCP Plan if required as specified under 8-201.13(A) that includes the information specified under §8-201.14 as it is relevant to the Variance requested.

### **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 §3-401.11(D)(4), §3-502.11, or 4-204.110(B); 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.

### **8-201.14 Contents of a HACCP Plan.**

For a Food or Eating 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 Potentially Hazardous Foods (Time/Temperature Control for Safety Foods) 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 and 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,
  - (2) The Critical Limits for each Critical Control Point,
  - (3) The method and frequency for monitoring and controlling each Critical Control Point by the Food Employee designated by the Person in Charge,
  - (4) The method and frequency for the Person in Charge to routinely verify that the Food Employee is following standard operating procedures and monitoring Critical Control Points,
  - (5) Action to be taken by the Person in Charge if the Critical Limits for each Critical Control Point 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; 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.



#### IV. 2013 Maine Food Code HACCP/Variance Requirements Table

Product/process	Example	Code reference	HACCP	Variance
Smoking Food as a method of Food preservation rather than as a method of flavor enhancement	Smoking fish or meat to extend shelf life	3-502.11 (A)	x	x
Curing food	Cured meat	3-502.11 (B)	x	x
Using Food additives or adding components such as vinegar as a method of food preservation rather than flavor enhancement or, to render a Food so that it is not a Potentially Hazardous Food (Time/Temperature Control for Safety Food)	Pickles	3-502.11 (C)	x	x
Packaging Food using a Reduced Oxygen Packaging method except where the growth of, and toxin formation by Clostridium botulinum; and the growth of Listeria monocytogenes are controlled as specified under 3-502.12	Vacuum packaging cooked foods) (or any other product not defined in 3-502.12)	3-502.11 (D)	x	x
Operating a Molluscan Shellfish life-support system display tank used to store or display shellfish that are offered for human consumption.	Clams, mussels, oysters held alive in a tank	3-502.11(E) 4.204.110	x	x
Custom processing animals that are for personal use and not for sale or service in a Food or Eating Establishment	Using a commercial kitchen to process deer	3-502.11 (F)	x	x
Preparing Food by another method that is determined by the Regulatory Authority to require a variance	Any potentially risky food process not covered by the code.	3-502.11 (G)	x	x
Sprouting seeds or beans	Bean sprouts grown on site	3-502.11 (H)	x	x
Packaging food using reduced oxygen packaging as described in 3.502.12 where the food has an Aw of 0.91 or less.	Vacuum packaging dried foods	3-502.12 (B) (2) (a)	x	
Packaging food using reduced oxygen packaging as described in 3.502.12 where the food has a pH 4.6 or less.	Vacuum packaging blueberries or other high acid fruit	3-502.12 (B) (2) (b)	x	
Packaging food using reduced oxygen packaging as described in 3.502.12 where the food is a Meat or Poultry product cured at a Food Processing Plant regulated by the USDA using substances specified in 9 CFR 424.21 and is received in an intact Package.	Re-packing (using ROP) meat cured at a USDA plant	3-502.12 (B) (2) (c)	x	
Packaging food using reduced oxygen packaging as described in 3.502.12 where the food is a food with a high level of competing organisms such as raw meat, raw poultry or raw vegetables.	Vacuum packaging raw meat, raw poultry, or raw vegetables	3-502.12 (B) (2) (d)	x	
Packaging food using reduced oxygen packaging as described in 3.502.12 where the food is fish that is frozen before, during, and after packaging.	Vacuum packaging frozen fish	3-502.12 (C)	x	
Packaging food using reduced oxygen packaging as described in 3.502.12 where the food is packaged using a cook chill or sous vide process.	Vacuum packaging cook chill products	3-502.12 (D)	x	
Packaging food using reduced oxygen packaging as described in 3.502.12 where the food is a cheese that is commercially manufactured in a Food Processing Plant, has no ingredients added in the Food Establishment, and that meets the Standards of Identity specified in 21 CFR 133.150 (Hard Cheeses), 21 CFR 133.169 (Pasteurized process cheese) or 21 CFR 133.187 (Semisoft cheeses).	Vacuum packaging cheese	3-502.12 (E)	x	
A raw animal food that is not cooked to the specifications in 3-401.11 (A) or 3-401.11 (B)	Any alternative cooking process that does not meet the temperature requirements of the code. Undercook/raw without CA.	3-401.11(D)(4)	x	x
Unpackaged juice that is prepared for service or sale in a Ready-to-Eat form that is served to a Highly Susceptible Population.	Apple cider pressed on site and served in a preschool.	3-801.11 (A) (3)	x	

**X= needs either a HACCP Plan, Variance or Both**

**GREEN=ACIDIFIED    YELLOW= NOT COMMON    PINK= CURING    BLUE= ROP**

## V. HACCP Plan contents

From: 8-201.14 Contents of a HACCP Plan.

- **Categorization** of the types of Potentially Hazardous Foods (Time/Temperature Control for Safety Foods). Examples: soups and sauces, salads, and bulk, solid Foods such as Meat roasts, or of other Foods that are specified by the Regulatory Authority.
- A **Flow Diagram** by specific Food or category type identifying Critical Control Points and providing information on the following:
  - Ingredients, materials, and Equipment used in the preparation of that Food, and
  - Formulations or recipes that delineate methods and procedural control measures that address the Food safety concerns involved.
- Food Employee and supervisory **Training plan** that addresses the Food safety issues of concern.
- A statement of **Standard Operating Procedures** for the plan under consideration including clearly identifying:
  - Each **Critical Control Point**,
  - The **Critical Limits** for each Critical Control Point,
  - The method and frequency for **Monitoring** and controlling each Critical Control Point by the Food Employee designated by the Person in Charge,
  - The method and frequency for the Person in Charge to routinely **Verify** that the Food Employee is following standard operating procedures and monitoring Critical Control Points,
  - **Corrective Actions** to be taken by the Person in Charge if the Critical Limits for each Critical Control Point are not met, and
  - **Records** to be maintained by the Person in Charge to demonstrate that the HACCP Plan is properly operated and managed; and
- **Additional scientific data or other information**, as required by the Regulatory Authority, supporting the determination that FOOD safety is not compromised by the proposal.

### \*\* Notes:

- **Although not required by our Maine Food Code, it is highly recommended that before engaging in an activity that requires a HACCP plan, please reach out to your inspector. They will be able to provide you with guidance and templates of HACCP plans.**

## VI. Variance requirements and Process

Before a Variance from a requirement of this Code is Approved, the information that shall be provided to the Department by the person requesting the Variance includes:

- A **HACCP Plan** if required as specified under ¶ 8-201.13(A) that includes the information specified under §8-201.14 as it is relevant to the Variance requested.
- An **analysis of the rationale** for how the potential public health Hazards and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal.
  - The HACCP plan then needs to be sent to the University of Maine Cooperative Extension, who will review the process and plan and conduct sample testing of the product. 207-581-3188. [extension@maine.edu](mailto:extension@maine.edu).
- A completed variance form of the proposed **Variance** of the Code requirement citing relevant Code section numbers and a statement of how the potential public health hazard will be addressed. Request current variance form from your inspector.

### \*\* Notes:

- If the Eating Place/Eating Establishment is wholesaling, they will need to contact the Department of Agriculture, Forestry and Conservation at 207.287.3841.
- Variances will be issued for only the following specialized food processes: Curing with the addition of nitrites only, acidification of canned foods, fermenting of vegetables, and preparation of sushi rice.
- Due to the complexity of the process and HACCP plan, the Health Inspection Program will not approve variances for: The fermenting of meats, smoking of foods as a method of food preservation, and the reduced oxygen packaging of fresh seafood and fish products.

## VII. Contact Information and Links

HIP List of Food Safety Consultants

<https://www.maine.gov/dhhs/mecdc/environmental-health/el/training.htm>

University of Maine Cooperative Extension

207-581-3188. [extension@maine.edu](mailto:extension@maine.edu)

Department of Agriculture, Forestry and Conservation

207.287.3841

The University of Maine - Cooperative Extension Publications. *Bulletin #3107, Reduced Oxygen Packaging (ROP): Requirements and Guidelines in Maine for Food Service.*

<https://extension.umaine.edu/publications/3107e/>

AFDO - HACCP Plans for Specialized Processes at Retail

[Guidance for Developing HACCP Plans for Specialized Processes at Retail – Association of Food and Drug Officials \(afdo.org\)](#)

AFDO presentation by Tom Nerney, FDA. *FDA Food Code Requirements for ROP*

[https://www.afdo.org/wp-content/uploads/2024/02/HACCP\\_Validation\\_and\\_Field\\_Verification.pdf](https://www.afdo.org/wp-content/uploads/2024/02/HACCP_Validation_and_Field_Verification.pdf)

FDA Critical Control Point Decision Tree

[Fish and Fishery Products Hazards and Controls Guidance Fourth Edition – June 2021 Appendix 3: Critical Control Point Decision Tree \(fda.gov\)](#)

FDA – Hazard Analysis Critical Control Point (HACCP)

<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/hazard-analysis-critical-control-point-haccp>