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

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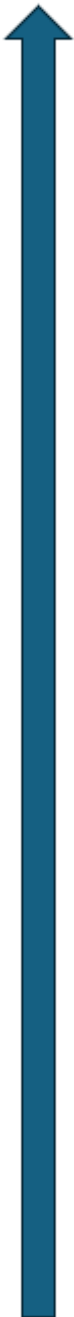
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I. Purpose

For HACCP plans and variances for the processes identified below with arrows and in **BLUE**, the purpose of this guidance document is to answer frequently asked questions 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.

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Variance w/ HACCP

- **3-502.11:** Curing, custom processing animals for personal use, sprouting beans or seeds, smoking for preservation, additives to preserve or make non-TCS, molluscan life support system, ROP w/o controls of 3-502.12, other processes determined to need it (e.g. some dehydration).
- **3-401.11(D)(4):** Undercooking animal food w/o a Consumer Advisory.

HACCP

- **3-502.12:** ROP with controls against C. Bot and L. Monocytogenes such as: for storage, cook-chill, sous-vide, cheese, fish that is frozen before, during and after packaging.

Plans and Procedures

- **3-401.14(F):** Written procedures for Non-Continuous Cooking
- **3-501.19(A)(1):** Written procedures for TPHC
- **3-301.11(E)(2)(a):** Written procedures for BHE-RTE (also requires prior approval and a written employee health policy)
- **8-201.12(E):** Applicants are required to have standard procedures that ensure compliance with the requirements of this Code are developed or are being developed.

Processes Not Needing Increased Scrutiny

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 packaging 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. HIP is the primary licensing 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*.

Reduced Oxygen Packaging (ROP) is the 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 the Maine Food 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

(with updated allowances and information of the 2022 FDA Food Code)

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 **TIME/TEMPERATURE CONTROL FOR SAFETY** 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.

(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.

(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) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded; or

- (iii) 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 7 days, not to exceed 30 days from its date of 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) 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.

(F) A HACCP Plan is not required when a food establishment uses a reduced oxygen packaging method to package time/temperature control for safety food that is always:

(1) Labeled with the production time and date,

(2) Held at 5°C (41°F) or less during refrigerated storage, and

(3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after 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.

8-103.12 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.

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) Before engaging in REDUCED OXYGEN PACKAGING without a VARIANCE as specified under § 3-502.12, a PERMIT applicant or PERMIT HOLDER shall submit a properly prepared HACCP PLAN to the REGULATORY AUTHORITY.

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 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. Specialized Processes

From 3-502.11 and 3-401.11(D)(4):

The below processes require a **Variance** and a **HACCP Plan**:

- **Smoking Food** as a method of Food preservation rather than as a method of flavor enhancement
- **Curing Food**
- Using **Food Additives or adding components** such as vinegar:
 - As a method of Food preservation rather than as a method of flavor enhancement, or
 - To render a Food so that it is not Potentially Hazardous Food (Time/Temperature Control for Safety Food)
- Operating a **Molluscan Shellfish life-support system display tank** used to store or display shellfish that are offered for human consumption
- **Custom processing animals that are for personal use** as Food and not for sale or service in a Food or Eating Establishment
- **Sprouting seeds or beans**
- **Preparing Food by another method that is determined by the Regulatory Authority to require a Variance***
- 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.

The below process only requires a **HACCP Plan** if complying with §3-502.12 to control the growth of Clostridium botulinum and Listeria monocytogenes:

- **ROP of TCS Foods** (e.g., for storage, cook-chill, sous-vide, cheese, fish that is frozen before, during and after packaging)

* Dehydration of a TCS food item requires variance. The heat treatment of any plant food will render it a TCS food unless it falls under the table below being identified as non-TCS and does not require a HACCP plan or variance.

Table B. Interaction of pH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_w VALUES	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	Non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	Non-TCS food	Non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	Non-TCS food	Non-TCS food	PA	PA
> 0.92	Non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

X= needs either a HACCP Plan, Variance or Both

GREEN=ACIDIFIED

YELLOW= NOT COMMON

PINK= CURING

BLUE= ROP

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.		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.		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), 3-401.11 (B), 3-401.11 (C)	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	
Dehydration of a TCS food requires a variance. The heat treatment of a plant food will render it a TCS food unless it falls under table B (in definition of a PHF/TCS food) being identified as non-TCS.		3-502.11(G)	x	x

V. HACCP Plan contents

(with updated allowances and information from the 2022 FDA Food Code)

HACCP Plan Content Requirements for All Specialized Processes

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.
- **Additional scientific data or other information**, as required by the Regulatory Authority, supporting the determination that FOOD safety is not compromised by the proposal.
- A statement of **Standard Operating Procedures** [(8-201.14(D))] 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.

Additional Information for ROP of TCS Foods

From: 3-502.12(B) Reduced Oxygen Packaging, Criteria

If packaging **TCS** food using a **Reduced Oxygen Packaging** method, the HACCP Plan shall contain the information specified under 8-201.14(D)(**SOP**) **and**:

- **Identifies** the Food to be Packaged;
- Except as specified under C-E (*C, frozen fish; D, cook-chill and sous vide; E, cheese*) of this section, requires that the Packaged Food shall be **maintained at 41°F or less and** meet at least one of the following criteria:
 - (*low water activity*) Has an AW of 0.91 or less,
 - (*low pH/acidic*) Has a pH of 4.6 or less,
 - (*prior cured*) 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
 - (*raw vegetables or animal foods*) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;
- 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:
 - Maintain the Food at 5°C (41° F) or below, and
 - 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;
- 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;
- Includes operational **procedures** that:
 - Prohibit contacting Ready-to-Eat Food with bare hands, as specified under 3-301.11(B),
 - Identify a designated area and the method by which:
 - Physical barriers or methods of separation of raw Foods and Ready-to-Eat Foods minimize cross contamination, and
 - Access to the processing Equipment is restricted to responsible trained personnel familiar with the potential Hazards of the operation, and
 - Delineate 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:
 - Concepts required for a safe operation,
 - Equipment and facilities, and
 - **Procedures** specified under Subparagraph (B)(5) (*above in green*) of this section and 8-201.14(D)(**SOP**).

Additional Requirements for Cook-Chill and Sous Vide

From: 3-502.12(D) Reduced Oxygen Packaging, Criteria

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

- Ensure the Food is:
 - 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,
 - **Cooked** to heat all parts of the Food to a temperature and for a time as specified under § 3-401.11 (cooking>raw animal foods),
 - **Protected from contamination** before and after cooking as specified under Parts 3-3 (*protection from contamination after receiving*) and 3-4 (destruction of organisms of public health concern),
 - 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),
 - **Cooled** to 5°C (41°F) in the sealed package or bag, as specified under § 3- 501.14, and subsequently:
 - 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;
 - **Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded; or**
 - **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 7 days, not to exceed 30 days from its date of PACKAGING, at which time the FOOD must be consumed or discarded; or**
 - Held frozen with no shelf life restriction while frozen until consumed or used.
 - **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,
 - 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
 - **Labeled** with the product name and the date packaged; and
- Maintain the **records** required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP Plan and:
 - Make such records available to the Regulatory Authority upon request, and
 - Hold such records for at least 6 months.

Additional Requirements for ROP of Fish

From: 3-502.12(C) Reduced Oxygen Packaging, Criteria

- 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.

Additional Requirements for ROP of Cheese

From: 3-502.12(E) Reduced Oxygen Packaging, Criteria

- A Food Establishment that **packages cheese using a Reduced Oxygen Packaging** method shall:
 - **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 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.);
 - Have a **HACCP Plan** that contains the information specified under 8-201.14(D) and as specified under 3-502.12 (B)(1), (B)(3)(a), (B)(5) and (B)(6);
 - **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
 - **Discards** the Reduced Oxygen Packaged cheese, if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

**** Notes:**

- **Although not explicitly required by our Maine Food Code, the Health Inspection Program is requiring the approval of a HACCP plan prior to engaging in the process requiring it, as stated in the 2022 FDA Food Code.**

VI. Variance Requirements

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.
 - *(Processes to create a food product that requires a variance will need to have a product assessment. It is recommended to contact the University of Maine Cooperative Extension for a Product Assessment. 207-581-3188. 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 a 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

Cornell College of Agriculture and Life Sciences

<https://cals.cornell.edu/cornell-agritech>

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

AFDO HACCP Verification Audit Checklist and Marking Guidance

<https://www.afdo.org/haccp-plan-review/resources/>

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>

USDA – pH of Selected Foods

<https://pmp.errc.ars.usda.gov/phOfSelectedFoods.aspx>

VIII. Approval of HACCP Plans and Variances

Although not explicitly required by our Maine Food Code, the Health Inspection Program is requiring the approval of a HACCP plan prior to engaging in the process requiring it, as stated in the 2022 FDA Food Code.

Both the current FDA Code and Maine Food Code require variance approval prior to an establishment producing foods under such processes.

If an inspector is not comfortable with reviewing a HACCP plan due to lack of experience or complexity, they should not. Please send to your respective Inspector Supervisor for them to review or assign.

Experience has shown that poorly designed HACCP plans can take far too many hours to review and properly identify errors. The process can quickly turn into the inspector essentially designing the plan for the establishment. Therefore, the Program's position over the years is if the submitted HACCP plan is of poor quality the Program may request the establishment employ a specialist to assist them.

For the well-prepared HACCP plans, please see Appendix A for a checklist to be filled out. If satisfactory, the second part, the approval form, must be filled out.

If there is a variance required in addition to the HACCP plan, please send all pertinent information to your Inspector Supervisor. This would include: the HACCP checklist and approval form (Appendix A), the HACCP plan, the product assessment (if applicable, likely from UMaine Coop Ext), and the variance request form (Appendix E). After review by your Inspector Supervisor, they will forward to the Program Manager.

IX. HACCP Plan Templates

Care should be taken when providing templates and examples of HACCP plans that were designed or modified by HIP staff. Experience has shown that some operators will take the HACCP plan template and begin operating the specialized processes. They forgo designing their own HACCP plan. When confronted with their lack of design they have on occasion attempted to turn the blame onto the inspector for any errors or omissions. They believe, or claim to believe, that the Program provided a complete plan with no further action needed.

It is recommended that if templates or examples are provided to establishments it is done with consultation as well. Further, use the opportunity to impress upon them that it behooves them to submit the finished plan for approval before implementing.

If any HACCP templates or examples are attached to this guidance, they will be in Appendix F.

X. Field Verification Audit Policy

Introduction:

Due to the increased risks to public health presented by specialized process requiring a HACCP plan or HACCP plan and variance, it is essential to conduct verification audits. A verification audit is a form of compliance inspection that is specifically focused on the requirements of the HACCP plan or HACCP plan and variance. Verification audits can be conducted as a stand-alone compliance inspection or can be conducted in conjunction with other compliance inspections or investigations.

Debiting:

The violations noticed during the audit are debited into the inspection report. If auditing the establishments HACCP/variance compliance as stand-alone inspection, use a partial follow-up inspection type.

Appendix B is the Field Verification Audit. It contains tables to determine compliance of the pertinent Code sections. In addition, there is some advice on Remote Form debiting on page 4.

Frequency:

After approving a HACCP plan, the inspector will notify the HIP Compliance Specialist. The Compliance Specialist will maintain a spreadsheet to track the establishment's verification due dates. If a plan requires a variance, the inspector will still notify the Compliance Specialist so that they may create a record with the understanding that the Verification Audit frequency will not be established until the variance is approved.

After the initial approval of a plan, there will be at least a 1-month (Risk Category 6), 3-month (Risk Category 5), and 1-year (Risk Category 4) verification audit. If any of the audits are deficient, others must be scheduled. Once the establishment has demonstrated proficiency in operating under their plan, they will continue under a necessary yearly verification audit.

Corrective Actions, Enforcement, Discarding of Food, and Embargo:

Noncompliance with a HACCP plan or variance will necessitate corrective actions, short-term and long-term. Appendix C is provided for guidance in these instances. It is a table that is slightly modified from one provided by the AFDO.

If short-term corrective actions cannot be taken, the inspector will likely request that the food in question be discarded. When unsure if discarding is needed, or quantity of food is large, the inspector should contact their supervisor for advice. As with other violations, the inspector has some discretion. If leniency is given, it should be given cautiously. The inspector must clearly state their justification in the associated paperwork.

The inspector will have to place the food under embargo if the establishment refuses to discard food when requested. Please see Appendix D for guidance.

Documentation Retention:

The approved plan will be sent to the Compliance Specialist. The Compliance Specialist will save in the G Drive in the HACCP file

XI. Field Verification Audit Policy

- A. HACCP Plan Review Checklist and Approval Form
- B. Filed Verification Audit Checklist
- C. Corrective Action Table
- D. HACCP Embargo Procedures, Documentation, and Information
- E. Variance Request Form
- F. HACCP Plan Examples (reserved)