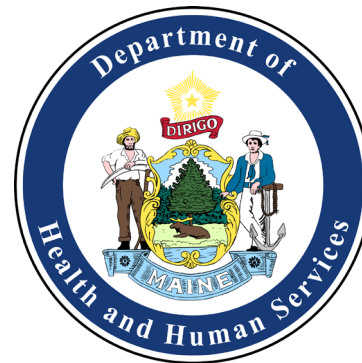


HACCP and Variances in Maine: Our Progress with Training and our Resources

Joel Demers

Public Health Inspector Supervisor



NEFDOA Conference

11-14-24

HACCP in Maine Talking Points

➤ Situation and Challenges

➤ Current Focus of Staff Education:

Place Good Info in the Same Location (consolidate vs. firehose)

- Who needs HACCP and Variances
- What is needed for HACCP and Variances
- Resource and contact list
- Verification Information for Inspectors

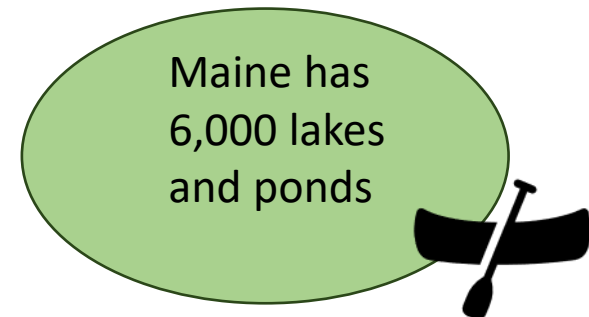
Reorganizing/Reformatting of Info When Needed

- Making easier to read and understand

➤ Our Resources = UMaine Coop Extension

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Situation and Challenges

- All wholesale is licensed by the Department of Agriculture, Conservation, and Forestry.
- 2 state inspector supervisors, 15 state inspectors, and 4 municipal health inspector
 - ❑ Each state inspector manages ~400 retail food establishments.
- Many of our inspectors have **zero HACCP plans** operating in their Districts.
 - ❑ Portland has the most with only ~9 at any given time.
- Our staff HACCP knowledge is a work in progress and likely lagging larger more experienced states



Including tidal inlets, Maine has 3,478 miles of coastline. Almost 2,000 miles more than Mass

Training: Place Info into the Same Location

Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
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) 287-9058
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
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- VII. Resources, Links, and Contact information for UMO, DACF, USDA, and food safety consultants.

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	

Restaurant and food service industry jobs = 10% of the total jobs in Maine.

HACCP Field Verification Audit

Facility name:	RFE Permit/License Number:
Address:	Person In Charge:
Process Reviewed:	Person(s) interviewed:
Date of written plan approval:	Amended since approval? Yes No
Inspector:	Date of Audit:
Inspection type: <input type="checkbox"/> Pre-approval	<input type="checkbox"/> Routine Verification <input type="checkbox"/> Follow-up

Facility Overview and General HACCP Criteria/Observations

Space in each comment field will expand as needed to accommodate as much data as is required. Additional rows may be added to each section or deleted from each section as needed.

A. Processes Reviewed (All regulatory citations are based on the current version of the FDA Food Code.)

Must complete the process-specific lettered section of this form (in the following pages) for each applicable process.

<input type="checkbox"/> Section H: ROP for storage of raw proteins or cheeses	<input type="checkbox"/> Section N: Sprouting
<input type="checkbox"/> Section I: ROP – Sous Vide cooking	<input type="checkbox"/> Section O: Custom Processing
<input type="checkbox"/> Section J: ROP Cook-Chill	<input type="checkbox"/> Section P: Molluscan Shellfish Tanks
<input type="checkbox"/> Section K: ROP – Other ROP packaging per 3-502.11(D)	<input type="checkbox"/> Section Q: Processing Juice
<input type="checkbox"/> Section L: Curing for preservation 3-502.11(A-C)	<input type="checkbox"/> Section R: Other processing methods per 3-502.11(G) requiring HACCP – specify:
<input type="checkbox"/> Section M: Acidification/Fermentation/Additives	

Practices, products and equipment observed in the kitchen reflect the HACCP plan as approved		
A working copy of each approved HACCP plan is available for daily use.		
Storage and display – shelf life and expiration dates meet requirements of the approved plan		
Monitoring Records required by HACCP plan are current and available		
Other:		

Comments:		
-----------	--	--

B. Establishment has implemented effective Pre-Requisites (Document violations on Food Establishment Inspection Report.) 8-103.12(A)

	Yes	No	
Training 8-201.14(E)(1)	The RFE has a training program supporting all aspects of the plan.		
	The food safety issues of concern are included in training.		
	Is training provided whenever appropriate, is it documented, and are records available?		
	Employee correctly demonstrates relevant calibration procedures and pH, temperature, or other CCP measurements for inspector.		
Employee Health and Hygiene Policies 2-103.11(P), 2-2, 2-3, 2-4	The RFE has an Employee Health Policy that includes a written plan for exclusion, restriction and reinstatement.		
	The RFE has an Employee Hygiene Policy that meets requirements of Food Code 2-2, 2-3.		
	Bare-hand contact with ready-to-eat (RTE) foods is prohibited, per Food Code 3-301.11(B).		
Sanitation Procedures (SSOP) 2-201.14(E)(3)	A procedure and schedule or frequency are provided for cleaning and sanitizing equipment used in the approved process.		

HACCP Field Verification Audit

Marking Guidance

Food Code Reference	Foodborne Illness Risk Factors and Public Health Interventions	Corrective Action-Corrected During Inspection, Verification, Enforcement Action	Intervention for Long-term Compliance
3-404.11(A)(B)	Conformance with Approved Procedures:	3-404.11 (A) - PIC must provide documentation or discard the food. 3-404.11(B) - Properly label or discard the food.	3-404.11(A) - Contact local regulatory authority for guidance. Obtain approved HACCP plan. (B) - Train employees to label properly.
3-502.11 (A)(B)(C)(D)(E)(F)(G)(H)	Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan.	3-502.11 (A)(B)(C)(D)(E)(F)(G)(H) Discard the food	3-502.11(A)(B)(C)(D)(E)(F)(G)(H) Contact local regulatory authority for guidance. Obtain variance.
3-502.12(A)(B)(C)(D)(E)	Violation of Conformance with approved procedures results in violation on this item and the HACCP process that is being violated.	3-502.12 (A)(B)(C)(D)(E) - Provide documentation or discard the food.	3-502.12(A) - Obtain documentation. (B) - Obtain approved HACCP plan. Obtain required documentation. (C) - Train employees. (D) - Obtain approved HACCP plan. Train employees. (E) - Change source. Obtain approved HACCP plan. Train employees to properly label and discard.
4-204.110(A)(B)		4-204.110 (A) - Discontinue service of the food. Label tank properly. (B) - Discard the food	4-204.110(A)(B) - Contact local regulatory authority for guidance. Obtain approved HACCP plan.

HACCP Field Verification Audit

Marking Guidance

8-103.12(A)(B)		8-103.12 (A) - Discard the food (B) - PIC must provide documentation or discard the	8-103.12(A) - Train employees. (B) Make records available. Obtain additional copies of records
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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

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>

Maine has 23.41
Billion live trees
as of 2019

Training: Reorganizing/Reformatting of Info when Needed

IV. HACCP Plan contents

(with updated allowances due to newer versions of the 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.

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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 5oC (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).

Maine has only 44
people per sq mile.
The least in NE.

RI has 1,059!



Additional Information 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;
 - 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;
 - 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
 - Held frozen with no shelf life restriction while frozen until consumed or used.
 - **Cook chill and sous vide foods may be held for 7 days at 41F after cooling to 41F**
 - **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 Information on 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 Information on 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.

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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 process info and product then need to be sent to 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 current variance form from your inspector.

Portland was
Bon Appetit City
of the Year in
2018

From: AFDO - HACCP Field Verification Audit

Marking Guidance

Food Code Reference	Foodborne Illness Risk Factors and Public Health Interventions	Corrective Action- Corrected During Inspection, Verification, Enforcement Action	Intervention for Long-term Compliance
3-404.11(A)(B) [Juice, absent in 2013 MFC]	Conformance with Approved Procedures:	(A) - PIC must provide documentation or discard the food.	(A) - Contact local regulatory authority for guidance. Obtain approved HACCP plan.
		(B) - Properly label or discard the food.	(B)- Train employees to label properly.
3-502.11 (A)(B)(C)(D)(E)(F)(G)(H) [Variance Required]	Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan.	(A)(B)(C)(D)(E)(F)(G)(H) - Discard the food	(A)(B)(C)(D)(E)(F)(G)(H) - Contact local regulatory authority for guidance. Obtain variance.
3-502.12(A)(B)(C)(D)(E) [ROP Criteria]	Violation of Conformance with approved procedures results in violation on this item and the HACCP process that is being violated.	(A)(B)(C)(D)(E) - Provide documentation or discard the food.	(A) - Obtain documentation. (B) - Obtain approved HACCP plan. Obtain required documentation. (C) - Train employees. (D) - Obtain approved HACCP plan. Train employees. (E) - Change source. Obtain approved HACCP plan. Train employees to properly label and discard.
4-204.110(A)(B) [Molluscan Shellfish Tanks]		(A) - Discontinue service of the food. Label tank properly.	(A)(B) - Contact local regulatory authority for guidance. Obtain approved HACCP plan.
		(B) - Discard the food	
8-103.12(A)(B) [Conformance with Approved Procedures]		(A) - Discard the food	(A) - Train employees.
		(B) - PIC must provide documentation or discard the food	(B) Make records available. Obtain additional copies of records.
8-201.14(A)(B)(C)(D)(E) [Contents of a HACCP Plan]	(A)(B)(C)(D)(E) – PIC must provide documentation or discard the food.	(A)(B)(C)(D)(E) - Obtain a HACCP plan. Alter existing HACCP plan.	

Our Resources

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

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>

Highest value agricultural product in Maine? Potatoes. \$176.4 million of sales in 2017.



Cooperative Extension: Food & Health

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Food Safety

[Training Opportunities](#)[Food Testing Services](#)[Food Safety Team](#)[Food Safety Videos](#)[Food Safety Home](#)

Food Business

[Assistance for Starting Home-Based Food Businesses](#)[Recipe to Market Program](#)

Food Testing Services

About our Food Testing Services and an overview of our process

We offer a team approach to provide food testing services and specialize in working with small and start-up food businesses. While our primary mission is to support Maine and New Hampshire food businesses, we also work with businesses across the U.S. Our process involves the online submission of your batch recipe, detailed processing methods, and one (1) sample sent to us in the final product container ([submission details listed below](#)).

Our Team

- **Dr. Beth Calder**, an FDA-recognized process authority for acid/acidified canned food products and primary contact for questions regarding testing, test results, and process reviews. Beth reviews the test results, the submitted recipe formulations, and the processing steps, and writes individualized and comprehensive review letters back to clients. The review letters are automatically emailed to the client as soon as they are completed.

What products can be sent to us for testing?

We provide testing and process reviews on shelf-stable, canned foods (acid and acidified), lacto-fermented vegetable products (except kombucha), water-activity controlled dessert sauces, frostings/fillings, high moisture baked goods, and minimally processed dried food products. **Buttercream frostings, baked goods, and fermented foods must be scheduled ahead of time with Beth before being mailed in.**

Fees (after May 15, 2024)

Maine Clients:

- **\$100** (per new product submission)
- **\$80** (per resubmission)

Non-Maine Clients:

- **\$160** (per new product submission)
- **\$140** (per resubmission)

04/20/2022

Cara Stadler
dba Tao Yuan Restaurant
22 Pleasant Street
Brunswick, ME 04011

RE: Testing Results - Order #1506
Product - Hot sauce, habanero in 5.00 oz Glass bottle with plastic screw on cap, dipper insert, styrofoam liner

Dear Client:

Enclosed you will find the test results performed on the sample you submitted for testing. **Please carefully review this letter and retain this letter for your records.** You must follow the formulation submitted to us for this review and the processing methods and critical factors outlined in this letter to ensure the microbiological safety of your product. If your product needs to be reformulated, please make the necessary adjustments and resend the product to us for testing. After the process review, if you decide to change the packaging, size of container, heating methods/process, ingredients, type and strength of acidulant, and/or headspace, you need to resend the product for another process and product review.

Additional requirements for food processors:

You **must** follow the updated Good Manufacturing Practices in 21 CFR 117 and includes keeping records of sanitation training for you and your employees: <https://www.fda.gov/Food/GuidanceRegulation/CGMP/default.htm>.

- This website links to a sanitation fact sheet that discusses proper sanitation practices: <http://edis.ifas.ufl.edu/19077>.
- You must use food grade detergents/sanitizers and use the concentration recommended by the manufacturer for sanitizing food contact surfaces. If you decide to use bleach as a sanitizer, you must purchase "Germicidal Bleach" and do not exceed 200 ppm for food contact surfaces. The concentration needs to be verified with a validated process, such as a titration kit or test strips.
- Any containers that come in contact with your ingredients/food product must be made of food-grade materials.
- You must register your facility with the FDA (Form 2541): <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>.
- You must also read 21 CFR 117 that outlines the new FDA Food Safety Modernization Act Preventive Controls rules and regulations: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm> and <http://fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>.
- You will need to record in ink the batch code number and monitoring parameters (pH or water activity/Brix) as required in your review letter. All records must be kept for a minimum of **three years**. You should develop a recall plan so product can be recalled should a problem arise. For more information on recalls, please visit this FDA website: <https://fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.
- Product ingredients must be listed on your label in descending order based on formulation weight. Labels must include net contents (weight or volume). If the product contains commercial ingredients, these ingredients need to be listed in parenthesis next to the commercial ingredient on your product label. If the product contains any of FDA's identified 8 food allergens (including sulfites), you must comply with the Food Allergen Labeling Law.



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Bulletin #3107, Reduced Oxygen Packaging (ROP): Requirements and Guidelines in Maine for Food Service



By Jason Bolton, Ph.D. Assistant Extension Professor and Food Safety Specialist, University of Maine Cooperative Extension.

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Many food service and commercial food processors have begun using Reduced Oxygen Packaging (ROP) (e.g. vacuum packaging) to help extend the shelf life of food products. The use of these packaging technologies has several benefits but it is essential to know the serious food safety risks and Maine Food Code requirements associated with this type of packaging.



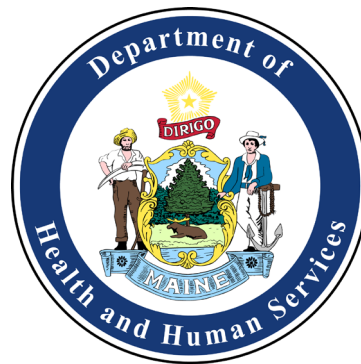
Photo by Stephen Ausmus

Maine exports ~100 million pounds of lobster a year. 80-85% of the US market.

Questions?

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“Maine has the best maple syrup in the country, way better than VT”
- Joel

