



BOH #20a Food Establishment Variances & HACCP

This **Checklist** highlights many of the requirements for Variances and HACCP Plans for Food Establishments under 105 CMR 590 and the FDA 2013 Merged Food Code. [Retail food | Mass.gov](https://www.mass.gov/info-details/retail-food) . **Remember: BOH always has the final say on requirements.**

With Thanks to the Massachusetts Environmental Health Association <https://maeha.org/regulator-guide-haccp/>

☐ The Massachusetts Food Code 8-103.10 & 11 Modifications and Waivers

With a few exceptions, anyone providing food to the public with or without compensation is required to have a permit to operate from the Board of Health (BOH). The BOH determines if the Food Establishment (FE) can vary any of the conditions of the Food Code as long as the variance does not create a health hazard or nuisance. Variances directly related to food processes will likely require a HACCP plan. Variances related to the Food Workers or Food Establishment facility may not require a HACCP. Written records must be retained by both the FE and the BOH.

☐ Definitions

- **Food Establishment:** Any vendor/facility/vehicle that stores, packages, prepares, sells, or distributes food to the consumer/public. It does not include places that only sell commercially packaged, non-TCS foods, home kitchens preparing non-TCS foods for a charitable event, cooking classes, private homes, an owner-occupied daycare, a small B & B or farm stands that sell unprocessed produce, maple syrup, eggs kept at 45F, and other unregulated foods.
- **Retail Food:** Any food product intended for human consumption and sold directly to the consumer. **Note: Animal Products also require a USDA certification to ensure the meat/animal products are from an approved/inspected source.**
- **Wholesale Food:** Any food product intended for human consumption sold to a vendor who sells to the consumer.
 - **Note: Wholesale Food operations require a permit from the Massachusetts Department of Public Health (DPH).**
- **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.
- **HACCP Plan:** means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

☐ Variances that don't require a HACCP but should have a written Risk Control Plan

- Variance/waiver for 3 Bay Sink requirement. 4-301.12 and others
- Variance for Food Manager Training 2-101.11(D)
- Note: BOH should not vary the requirement for a dedicated handwash sink if food is being processed or handled. The BOH may choose to not require a permit for a FE selling or distributing only a limited number of commercially packaged, shelf-stable foods.

☐ Food Vendors that Require a Board of Health Food Establishment Permit to Operate

- Any for-profit food vendor that makes or sells **processed** farm products, TCS foods, or foods that require refrigeration (except for whole eggs held at 45F) unless exempt.
 - Providing free tastes of any cut or prepared foods requires a food vendor/establishment permit unless exempted by the BOH.
 - Any non-profit selling Time-Temperature Control for Safety (TCS) foods – foods that require refrigeration, except for whole eggs held at 45F unless granted a temporary permit that does not exceed 14 continuous days at a single event.
 - Food processed or prepared anywhere but onsite at the point of sale or distribution, must be prepared in a permitted kitchen.
- Note:** non-profits that distribute food for free or for a minor handling charge may need a permit, but won't be charged a permit fee

☐ Specialized Processing Methods Requiring a Variance AND a HACCP Plan

Regulation § 3-502.11

A food establishment shall obtain a variance from the Board of Health as specified in § 8-103.10 and § 8-103.11 before conducting one or more of the following specialized processes. A HACCP plan is also required under § 8-201.13 and must be approved by the Board of Health before conducting a specialized process.

A) Smoking food as a method of preservation (rather than a method of flavor or color enhancement);

B) Curing food;

1. As a method of food preservation (rather than to enhance flavor) or

2. To render food so that it is not time/temperature control for safety (TCS)

C) Using food additives or adding components such as vinegar, such as acidification or fermentation)

D) Packaging Time/Temperature Control for Safety (TCS) food using a Reduced Oxygen Packaging (ROP) 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 establishment;
- G) Preparing food by another method that is determined by the Board of Health to require a variance, such as treating juice to achieve a 5-log reduction of pathogens; or
- H) Sprouting Seeds or Beans

☐ Specialized Processing Methods or Operations Requiring a HACCP Plan, but NO Variance

Treating Juice to Attain a 5-log Reduction of Most Resistant Microorganism of Public Health Concern

Regulation § 3-404.11

(A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.14(B) - (E) to attain a 5-log reduction of the most resistant microorganism of public health significance.

Reduced Oxygen Packaging (ROP) without a Variance, Criteria

Regulation § 3-502.12

(B): ROP packaged TCS food must control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes by meeting specific criteria.

(C): ROP packaged fish must be frozen before, during, and after packaging.

(D): ROP packaged TCS food using a cook-chill or sous vide process must meet specific criteria.

(E): ROP packaged specific cheeses must meet specific criteria.

☐ Specialized Processing Methods or Operations That DO NOT Require a Variance or a HACCP Plan

Treating Juice

Regulation ¶ 3-404.11 (B)

Unpasteurized juice that is not treated to yield a 5-log reduction of the most resistant microorganism of public health significance (not for HSP) may apply a warning statement on the package as specified under § 3-602.11 and in 21 CFR 101.17(g).

“WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.”

Reduced Oxygen Packaging (ROP) without a Variance, Criteria

Regulation ¶ 3-502.12 (F)

A HACCP plan **is not** required when a food establishment uses a reduced oxygen packaging method (ROP) for TCS food that is always

- labeled with the production time and date,
- held at or below 41°F during refrigerated storage, and

☐ Regulation: § 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 Board of Health’s file on food establishment includes:

- A statement of the proposed variance of the Code requirement citing relevant Code section numbers;
- 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
- 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.

☐ Regulation: § 8-103.12 Conformance with Approved Procedures

If the Board of Health 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 Board of Health, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;
 - Procedures for monitoring critical control points,
 - Monitoring of the critical control points,
 - Verification of the effectiveness of an operation or process, and
 - Necessary corrective actions if there is failure at a critical control point

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

1. A) Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the Board of Health for approval a properly prepared HACCP plan as specified under § 8-201.14 and the relevant provisions of this Code if:
 1. Submission of a HACCP plan is required according to law;

2. A variance is required as specified under § 3-502.11, ¶ 4-204.110(B), or ¶ 3-401.11(D)(3); or
 3. The Board of Health 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
2. B) A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under § 3-502.12.

Applicable Regulations - Specialized Processes or Operations Requiring a HACCP Plan

§ 3-404.11 Treating Juice Packaged in a Retail Food Establishment
 § 3-502.11 Variance Requirement
 § 3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria
 § 3-801.11 Pasteurized Foods and Prohibited Food in Highly Susceptible Populations
 § 8-103.10 Modifications and Waivers
 § 8-103.11 Documentation of Proposed Variance and Justification
 § 8-103.12 Conformance with Approved Procedures
 § 8-201.13 When a HACCP Plan is Required
 § 8-201.14 Contents of a HACCP Plan

☐ **Mass Food Establishment Requirements Checklist: BOH may pass more stringent requirements at any time.**

	All Commercial Mobile Food, Catering, Restaurants	Institutions Camps, Schools Hospitals/LTC	Non-Profit Venue Free Food Distribution	Non-Profit Multiple Events Non-TCS Foods	Non-Profit Fundraisers TCS Foods	Non-Profit Temporary Food Event	Residential Kitchen/NP for Free- or at cost Distribution
Permits	Yes	Yes	Yes	No*	Yes	Yes	No
Fees	Yes	Yes	No	No	Yes	Yes	No
Inspections	Yes	Yes	Yes	May	Yes	Yes	No
Choke Saver TR	Yes, 25+ seats	Yes, 25+ seats	Yes, 25+ seats	Yes, 25+ seats	Yes, 25+	Yes, 25+	N/A
Allergen Awareness Training/Signs	Yes**	Yes**, or have written plan	Yes**	Yes**	Yes**	No* recommend Signage	No, Soup Kitchen needs written plan.
Consumer Advisory Signs	Yes	Yes	Yes	N/A	Yes	Yes	N/A
Food Manager Training***	Yes	Yes	Yes	No*	Yes	No*	No*
Consumer Postings, Disclosures	Display Permit & Disclosures	Display Permit & Disclosures	Post Sign: <i>Food prepared in kitchens not regulated or inspected by the Board of Health</i>		Display Permit & Disclosures	Display Permit & Disclosures	N/A

*Food Managers Training, Allergen Awareness, Consumer Advisories are good practices and can be required by local BOH regulations. BOH can require additional Food Employee training at any time as deemed necessary for compliance.

**Allergen Awareness Notice: *Before placing your order, please inform your server if a person in your party has a food allergy.*

*****Every Food Establishment, including non-profits, must have a Knowledgeable Person in Charge (PIC) at all times.**

Consumer Advisory: Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; [Food Establishments at Events and Farmers Markets Questions and Answers \(07/25/19\)](#)

(mass.gov)<http://www.foodprotect.org/media/guide/Temporary%20Food%20Establishment%20Guidance%20Final%202011.pdf>