



## **Food Protection Program Policies, Procedures and Guidelines**

**Issue:** Licensure and Inspection Standards for Processing or  
Distributing Food for Sale at Wholesale

**No:** FP-04

### **I. Purpose**

The purpose of this policy is to establish objective and workable standards for the M.G.L. c. 94, § 305C licensure process for processing or distributing food for sale at wholesale. It is also intended to reduce the number of firms operating without a license while attempting to come into compliance and to reduce the number of re-inspections through the use of the administrative penalties to encourage compliance.

### **II. Operating Without a License**

There are a significant number of firms that fail to apply for licensure or that apply and are found unacceptable for licensure but that nevertheless continue to operate. To eliminate this limbo period, when firms operate while not licensed, the Food Protection Program shall implement the following procedures:

1. This portion of the policy applies to any firm operating without a license including, but not limited to:
  - (a) It never had a license;
  - (b) The facility moved to a new location or there is new ownership since the license is not transferable;
  - (c) The license expired without the timely submission of a renewal application;  
or
  - (d) The application is pending.
2. Upon discovery by the Department that a firm is operating without a license, a Food and Drug Inspector shall provide the firm with an application for licensure under 105 CMR 500.000, M.G.L. c. 94, § 305C, and conduct an inspection. As a result of the inspection, there are two courses of action:
  - (a) If the conditions at the facility do not constitute an imminent threat to the public health, or only a portion of the facility constitutes an imminent threat to the public health under (b) below, the inspector shall issue an Order to Correct and require the firm to submit the completed license application, Plan of Correction (POC) and fee to the Department within five calendar days of the inspection. The inspector shall also provide a notice to the facility stating

that if the Department is not in receipt of a completed application, POC and fee within five calendar days, the notice will constitute a cease and desist order, requiring that all operations cease to operate. It shall further state that the continued operation after five calendar days shall subject the facility to administrative penalties and further enforcement. Pursuant to 105 CMR 500.207 (D)(2)(b)(5) and (6), the penalty for failure to comply with a cease and desist order and the penalty for operating a facility without a license are \$500 per day of operation, respectively. Each violation and each day of noncompliance constitutes a separate \$500.00 penalty. The notice shall also state that if the Department commences an action for administrative penalties, penalties shall begin to accrue dating back to the first date that the Department can demonstrate that the facility operated without a license or violated the cease and desist order. Further enforcement by the Office of the Attorney General could follow, if the facility fails to apply for licensure and continues to operate.

(b) If the conditions at the facility constitute an imminent threat to the public health<sup>1</sup>, the inspector shall, after consulting with his/her supervisor (when available) and the Director or Assistant Director of the Food Protection Program (FPP), issue a Notice of Operating without a License and a Notice to Cease and Desist.

1) The cease and desist order shall state that continued operation shall subject the facility to administrative penalties and further enforcement. Pursuant to 105 CMR 500.207 (D)(2)(b)(5) and (6), the penalty for failure to comply with a cease and desist order and the penalty for operating a facility without a license are \$500 per day, respectively. Each violation and each day of noncompliance constitutes a separate \$500.00 penalty. Further enforcement by the Office of the Attorney General may also be appropriate. FPP shall contact the Department's Legal Office immediately upon issuance of a cease and desist order and/or an embargo order.

2) The products shall also be embargoed when they are or are suspected of being adulterated or misbranded. If only one part of the production is a risk, the inspector shall, after appropriate consultation, issue a cease and desist order for that portion of the operation that constitutes a threat, and shall embargo appropriate product. (The remainder of the facility would be considered under paragraph (a) above.)

3) The facility may decide to voluntarily cease its operation and voluntarily dispose of the product that would otherwise be embargoed. If the facility agrees voluntarily, the agreement shall be put in writing and the person in charge of the facility shall sign the agreement. In such instances, a cease and desist order is not necessary if the person in

---

<sup>1</sup> This shall include situations where the food is adulterated or misbranded or at risk of being adulterated or contaminated or where there are critical or excessive violations cited.

charge agrees to close until the Department issues a license for its operation.

3. If a facility timely applies within five calendar days, an inspector shall conduct a re-inspection for licensure. At this time there are two options the inspector may pursue, in consultation with his/her supervisor (when available) and the Director or Assistant Director of the FPP:

(a) Recommend the denial of the application if conditions at the facility do not meet the minimum standards defined in Part III, below, and issue a cease and desist order with the notice provisions described above.

(b) Recommend approval the application if conditions at the facility meet the minimum standards. The facility will be licensed if conditions at the facility meet a certain threshold. At the same time, the facility may be required to submit a second POC, as specified in paragraph III.A.4 below, and to correct the violations within the required time-lines, or be subject to administrative penalties as defined in 105 CMR 500.207 (D) and more fully described in Part II. For those violations that cannot be corrected within the required timelines, the applicant may petition the Department for an extended correction timeline.

### **III. Inspections**

This portion of the policy applies to all firms seeking an initial or renewal license under M.G.L. c. 94, § 305C and 105 CMR 500.000. The following standard is a more complete explanation of 105 CMR 500.207 (A) through (C), which permit the refusal to issue, suspension, or revocation of a license, respectively, for failure to comply with the provisions of 105 CMR 500.000.

#### **A. Initial Licensure Inspection**

A firm seeking an initial license is required to meet specific standards before a license to operate is issued. The Food Inspection Report utilized by the Department of Public Health/Food Protection Program (DPH/FPP) lists 69 standards for licensure.

1. Initial licensure shall be given only to firms that meet the following standards:

(a) No critical deficiencies;

(b) No more than seven (7) non-critical deficiencies and submission of an approved plan of correction.

2. A firm meeting the above-listed standard may be granted a license to operate. However, the firm shall be placed on notice that it may be subject to administrative penalties if corrections are not timely made.

3. Failure to meet the above listed standards may result in the denial of an initial application.

4. Applicants not meeting the above listed standards may be denied a license and informed that they do not meet the standards and are prohibited from operating. Applicants failing a re-inspection and wishing to be reconsidered for licensure must correct all violations and submit a new application and fee for licensure. Any applicant who operates after denial of the application may be subject to administrative proceedings.

## **B. Subsequent Inspections**

Firms holding a current, valid license from the Department are subject to periodic and random inspections. The results of these inspections may affect the firm's licensure status.

1. A licensee shall renew its license annually as required by law.
2. Licensed firms that fail to meet the licensure standards may be subject to appropriate administrative/enforcement proceedings:
3. Failure to timely submit an acceptable correction plan may be a basis for the Department to commence administrative/enforcement proceedings.
4. If upon re-inspection, after the submission of an acceptable plan of correction, the licensee is found not to have corrected the deficiencies as reported or additional violations are cited, the licensee may be subject to administrative/enforcement proceedings.

The Department may exercise its discretion at any time, and determine that administrative/enforcement proceedings are warranted based upon factors including, but not limited to: type and severity of a deficiency; prior history of the firm, type of operation (i.e., warehouse and/or processor); and quality of the plan of correction.