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OF WEST VIRGINIA  
SECRETARY OF STATE

TITLE 64  
LEGISLATIVE RULE  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR PUBLIC HEALTH

SERIES 43  
FOOD MANUFACTURING FACILITIES

**§64-43-1. General.**

1.1. Scope -- This legislative rule establishes the minimum requirements for the design, construction, management and operation of food manufacturing facilities.

1.2. Authority -- WV Code §§16-1-4 and 16-7-1.

1.3. Filing Date --

1.4. Effective Date --

1.5. Repeal and Replacement of Former Rules -- This rule repeals and replaces Department of Health rule, Bakery Regulations, 64CSR43, filed November 28, 1967 and effective December 29, 1967.

1.6. Applicability -- This rule applies to the owners and operators of food manufacturing facilities.

1.7. Enforcement -- This rule is enforced by the Commissioner of the Bureau for Public Health.

**§64-43-2. Definitions.**

2.1. Acidified foods -- Low-acid foods to which acids or acid foods are added. These foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity (aw) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled." Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and non-standardized food dressings and condiment sauces) that contain small amounts of low-acid foods and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, foods that are stored, distributed, and retailed under refrigeration, and fermented are excluded.

2.2. Commissioner -- Commissioner of the Bureau for Public Health or his or her designee.

2.3. Food Manufacturing Facility -- Any person that manufactures, processes, or packs food for human consumption. This term does not include: farms; facilities regulated by Bureau for Public Health Legislative Rule, Food Establishments, 64CSR17; and facilities under the regulatory authority of the West Virginia Department of Agriculture.

2.4. Low-acid foods -- Any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

2.5. Permit -- A document issued by the Commissioner to operate a food manufacturing facility.

2.6. Person -- An individual, partnership, association, syndicate, company, firm, trust, corporation, government corporation, institution, department, division, bureau, agency, or any entity recognized by law.

2.7. Processing Authority -- A person who has expert knowledge of thermal processing requirements for low-acid foods packaged in hermetically-sealed containers or has expert knowledge in the acidification and processing of acidified foods.

### **§64-43-3. Incorporation By Reference of The Federal Code of Regulations.**

3.1. The following portions of Title 21, CFR Food and Drugs dated April 1, 2009 are incorporated by reference:

3.1.a. Chapter 1 Part 110--Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food with the following exceptions:

3.1.a.1.--110.80(b)(3)(i); and

3.1.a.2.--110.80(b)(3)(iii).

3.1.b. Chapter 1 Part 113--Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers.

3.1.c. Chapter 1 Part 114—Acidified Foods

### **§64-43-4. General Requirements.**

4.1. Whenever a food manufacturing facility is constructed or altered and whenever an existing structure is converted to a food manufacturing facility, plans and specifications for the construction, altering, or conversion shall be submitted to the Commissioner for review and approval at least 45 days prior to the date a person intends to engage in business.

4.2. Facilities shall not begin manufacturing, processing or packing food for human consumption until the facility has obtained or completed:

4.2.a. A permit to operate from the Commissioner, as required in section 5 of this rule;

4.2.b. Label approval for all products from the West Virginia Department of Agriculture;  
and

4.2.c. Registration with the Food and Drug Administration (FDA) under the Public Health Security and Bio-Terrorism and Preparedness and Response Act of 2002. Exemptions shall be determined by the FDA.

4.3. Facilities manufacturing Low-acid Foods or Acidified Foods shall also comply with requirements set forth in the Code of Federal Regulations incorporated by reference in section 3 of this rule regarding processing authority and proper school requirements prior to manufacturing, processing or packing food for human consumption.

4.4. All facilities governed by this rule shall maintain process records, have a written recall procedure, and flow charts of products. These documents shall be readily available to the Commissioner.

4.5. If living or sleeping quarters are located on the premises, they shall be separated from rooms and areas used for food manufacturing facilities with complete partitioning and solid self-closing doors.

4.6. All facilities governed by this rule shall maintain refrigerated foods at 41° Fahrenheit or below as appropriate for the particular food involved.

4.7. All facilities governed by this rule shall maintain hot foods at 135° Fahrenheit or above.

#### **§64-43-5. Permits.**

5.1. A person shall not operate a food manufacturing facility within the State of West Virginia who does not possess a valid permit issued by the Commissioner.

5.2. A person shall apply, in writing, for a permit to operate a food manufacturing facility to the Commissioner on a form prescribed by the Commissioner.

5.3. A person shall apply for a permit at least 15 days before the date that the current permit expires or within 15 days of the date before the actual or proposed operation of the facility is to be effected.

5.4. Permits are not transferable and become invalid upon a change of ownership.

5.5. A permit to operate expires at midnight on the 30<sup>th</sup> day of June following the date of issuance.

5.6 The Commissioner may, without warning, notice, or hearing suspend a permit to operate a food manufacturing facility if the permit holder:

5.6.a. Does not comply with the requirements of this rule or if the operation of the food manufacturing facility constitutes an imminent public health hazard; or

5.6.b. Has been determined by the Commissioner to have obstructed or hindered the Commissioner in the proper discharge of his or her duties.

5.7. The permit holder shall post operational permits within the food manufacturing facility and make them readily available to the Commissioner.

**§64-43-6 Inspections**

The Commissioner shall conduct as many inspections as necessary to assure compliance with this rule.

**§64-43-7. Implementation.**

7.1. Food manufacturing facilities in operation at the time this rule becomes effective, and that meet Section 3 of this rule, are considered eligible for a permit to operate provided that any construction done after the effective date of this rule is in compliance with this rule.

7.2. New or extensively remodeled food manufacturing facilities whose plans and specifications received written approval from the Commissioner prior to the effective date of this rule are eligible for a permit to operate if the construction or remodeling is in compliance with the approved plans.

**§64-43-8. Fees.**

All facilities governed by this rule are subject to the appropriate fees established in the Bureau for Public Health Legislative rule, Fees for Service, 64CSR51, Appendix B.

**§64-43-9. Administrative Due Process.**

Any person adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests, or privileges shall do so in the manner prescribed in the West Virginia Department of Health's Procedural Rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.

**§64-43-10. Penalty for Violating Provisions of Rule.**

Any persons violating the provisions of this rule or orders pursuant to this rule is subject to the penalties provided in WV Code §§16-1-18 and 16-7-4.