



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

7/26/2018 11:59:30 AM

Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Health TITLE-SERIES: 64-43
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: 64-43 Food Manufacturing Facilities

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W. Va. Code §§16-1-4 and 16-7-1

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

Senate Bill 375 (Relating to Farmers Markets), enacted by the Legislature on March 10, 2018 and signed by the Governor on March 27, 2018, adds a new section to the West Virginia Code (W.Va. Code § 19-35-5) that purports to move the regulation of certain types of food manufacturing from the Bureau for Public Health to the West Virginia Department of Agriculture. This includes the regulation of cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods. The phrases cottage foods and other exempted food are not defined. West Virginia Code § 19-35-5 creates a carve out of the Bureaus authority to regulate all types of food manufacturing facilities, those facilities that involve the manufacturing of cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods, which are now under the jurisdiction of the West Virginia Department of Agriculture. Consequently, the Bureau proposes to amend the current to indicates that the Bureaus rule is inapplicable to cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods insofar as those foods and food products are regulated by the West Virginia Department of Agriculture pursuant to W.Va. Code § 19-35-5, including any legislative rules promulgated to implement the provisions of the section.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/20/2018

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/20/2018

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

N/A

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

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

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Senate Bill 375 (Relating to Farmers Markets), enacted by the Legislature on March 10, 2018 and signed by the Governor on March 27, 2018, adds a new section to the West Virginia Code (W.Va. Code § 19-35-5) that purports to move the regulation of certain types of food manufacturing from the Bureau for Public Health to the West Virginia Department of Agriculture. This includes the regulation of cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods. The phrases cottage foods and other exempted food are not defined. West Virginia Code § 19-35-5 creates a carve out of the Bureaus authority to regulate all types of food manufacturing facilities, those facilities that involve the manufacturing of cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods, which are now under the jurisdiction of the West Virginia Department of Agriculture. Consequently, the Bureau proposes to amend the current to indicate that the Bureaus rule is inapplicable to cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods insofar as those foods and food products are regulated by the West Virginia Department of Agriculture pursuant to W.Va. Code § 19-35-5, including any legislative rules promulgated to implement the provisions of the section

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

Senate Bill 375 (Relating to Farmers Markets), enacted by the Legislature on March 10, 2018 and signed by the Governor on March 27, 2018, adds a new section to the West Virginia Code (W.Va. Code § 19-35-5) that purports to move the regulation of certain types of food manufacturing from the Bureau for Public Health to the West Virginia Department of Agriculture. Consequently, the Bureau proposes to amend the current to indicate that the Bureaus rule is inapplicable to cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods insofar as those foods and food products are regulated by the West Virginia Department of Agriculture pursuant to W.Va. Code § 19-35-5, including any legislative rules promulgated to implement the provisions of the section This rule will have de minimis fiscal impact on the state.

B. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

N/A

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2018 Increase/Decrease (use "-")	2019 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0		0
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues	0		0

D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

This rule will have no fiscal impact on the agency.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Heather J Mcdaniel -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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

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. -- *W. Va. Code* §§16-1-4 and 16-7-1.

1.3. Filing Date. -- ~~April 21, 2011.~~

1.4. Effective Date. -- ~~April 21, 2011.~~

1.5. ~~Repeal and Replace. — This rule repeals and replaces Department of Health rule, Bakery Regulations, 64CSR43, filed November 28, 1967 and effective December 29, 1967. Sunset Provision. -- This rule shall terminate and have no further force or effect upon the expiration of five years from its effective date.~~

1.6. Applicability. -- This rule applies to the owners and operators of food manufacturing facilities. However, the provisions of this rule are inapplicable to cottage foods, acidified foods, non-potentially hazardous foods and other exempted foods insofar as those foods and food products are regulated by the West Virginia Department of Agriculture pursuant to *W.Va. Code* § 19-35-5, including any legislative rules promulgated to implement the provisions of the section.

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 acid(s) or acid food(s) 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 food(s) 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 Legislative Rule 64CSR17

“Food Establishments” 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. -- 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 such construction, altering, or conversion shall be submitted to the Commissioner for review and approval at least 45 days prior to the date the 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, it 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. No person shall operate a food manufacturing facility within the State of West Virginia who does not possess a valid permit issued by the Commissioner.

5.2. An application for a permit to operate a food manufacturing facility shall be made in writing 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 shall not be transferable and shall become invalid upon a change of ownership.

5.5. A permit to operate expires at midnight on the 30th 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. The permit holder has been determined by the Commissioner to have obstructed or hindered the Commissioner in the proper discharge of his or her duties.

5.7. Operational permits shall be posted within the food manufacturing facility and be 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 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 provided that 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 *W. Va. Code* §§16-1-18 and 16-7-4.