

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #2

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2010 JUN 10 AM 8:46

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

RULE TYPE: Legislative CITE AUTHORITY: WV Code §§ 16-1-4 and 16-7-1.

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 43

TITLE OF RULE BEING AMENDED: BAKERY REGULATIONS

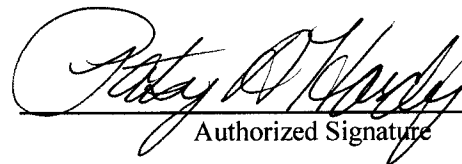
~~IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____~~

~~TITLE OF RULE BEING PROPOSED: FOOD MANUFACTURING FACILITIES~~

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 12, 2010 AT 12:00 noon ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Ann A. Goldberg, Director Public Health Regulations Bureau for Public Health 350 Capitol Street, Rm 702 Charleston, WV 25301 304 558-0035 Phone 304 558-1035 FAX ann.a.goldberg@wv.gov	Brad Cochran, Director Public Health Sanitation Bureau for Public Health Office of Environmental Hlth 350 Capitol Street 304 558-6730 phone 304 558-1291 FAX brad.j.cochran@wv.gov
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THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.


Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Legislative Rule, 64CSR43
Food Manufacturing Facilities
Department of Health and Human Resources
Bureau for Public Health
Office of Environmental Health Services

BRIEF SUMMARY

The proposed rule adopts by reference sections of the Federal Code of Regulations: Chapter 1 Part 110--Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food,. Chapter 1 Part 113--Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers, and Chapter 1 Part 114—Acidified Foods which establishes the minimum requirements for the design, construction, management and operation of food manufacturing facilities. This rule will also require a permit to operate a food manufacturing facility.

STATEMENT OF CIRCUMSTANCES

West Virginia currently does not have a comprehensive rule to govern Food Manufacturing Facilities. This proposed rule repeals and replaces current Legislative Rule 64CSR43 Bakery Regulations which has been effective since 1967 and is outdated. The proposed rule will continue to regulate bakeries and other facilities where food is manufactured, packaged or held for human consumption.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 64CSR43 "Food Manufacturing Facilities"

Type of Rule: X Legislative Interpretive Procedural

Agency: Health and Human Resources

Address: 1900 Kanawha Blvd. East
Bldg. 3, Room 206
Charleston, WV 25305

Phone Number: (304) 558-2971 Email: Ann.A.Spaner@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

This rule will allow for better oversight of food manufacturing facilities. Legislative Rule 64CSR51 "Fees for Services" which was amended during the 2010 Legislative Session, established permit fees for food manufacturing facilities. This rule has no fiscal impact on the Department of Health and Human Resources as it does not establish an additional fee, but rather established regulatory guidelines for these facilities.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2010 Increase/Decrease (use "-")	2011 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues	0	0	0

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Public Health Sanitation Division staff currently conduct approximately 125 annual food manufacturing facility inspections. A Food and Drug Administration (FDA) contract pays for 80 inspections. Prior to 2008, FDA paid for 50 annual inspections. Numerous site visits are made for new manufacturers to assure construction compliance.

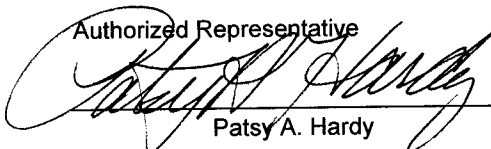
Date

6-8-10

Agency

Department of Health and Human Resources

Authorized Representative


Patsy A. Hardy
Cabinet Secretary

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

N/A

- f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Ann Goldberg, Director,
Public Health Regulations
350 Capitol Street, Rm. 702
Charleston, WV 25301
304 558-0035 - phone
~~304 559-1035 - fax~~
ann.a.goldberg@wv.gov

- g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Brad Cochran, Director, Public Health Sanitation
Office of Environmental Health Services
Bureau for Public Health
350 Capitol Street
Charleston, WV 25301
~~304 558-2981 phone~~
304 558-1071 fax
brad.j.cochran@wv.gov

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

n/a

b. Date of hearing or comment period:

From June 2010 to July 2010

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

n/a

d. Attach findings and determinations and reasons:

Attached n/a

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

**SERIES 43
FOOD MANUFACTURING FACILITIES**

FILED

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

§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 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 WV Code §§16-1-18 and 16-7-4.