

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

Form #3

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FILED

2010 JUL 29 AM 11:29

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

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

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

CITE AUTHORITY: §§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~~

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Patsy A. Hardy  
Authorized Signature

## 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.Goldberg@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)
<b>1. Estimated Total Cost</b>	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
<b>2. Estimated Total Revenues</b>	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.

[Empty box for explanation of estimates]

**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

July 30, 2010

Agency

Department of Health and Human Resources

Authorized Representative

Patsy A. Hardy  
Patsy A. Hardy  
Cabinet Secretary

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.

**QUESTIONNAIRE**

*(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)*

DATE: July 20, 2010

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) Ann A. Goldberg  
Bureau for Public Health  
350 Capitol Street, Rm. 702  
Charleston, WV 25301  
304 558-2971

LEGISLATIVE RULE TITLE: \_\_\_\_\_  
**FOOD MANUFACTURING FACILITIES 64CSR43**

1. Authorizing statute(s) citation \_\_\_\_\_  
**WV Code §§16-1-4, and 16-7-1**

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:  
June 10, 2010

b. What other notice, including advertising, did you give of the hearing?  
N/A

c. Date of Public Hearing(s) or Public Comment Period ended:  
June 10 to July 12, 2010

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached 2 comments  No comments received \_\_\_\_\_

- 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 10<sup>th</sup> 2010 to July 12<sup>th</sup> 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

Goldberg, Ann A

From: Peggs, Richard L  
Sent: Thursday, June 24, 2010 1:25 PM  
To: Cochran, Brad J; Goldberg, Ann A  
Cc: Whaley, Linda K  
Subject: RE: 64CSR43 FOOD MANUFACTURING FACILITIES - Comments

After re-reading Section 64 CSR 43 2.3, which states that Food Manufacturing Facilities ".....does not include....facilities under the regulatory authority of the West Virginia Department of Agriculture." That is probably sufficient for an exemption. Case closed.

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From: Cochran, Brad J  
Sent: Thursday, June 24, 2010 12:36 PM  
To: Goldberg, Ann A  
Cc: Whaley, Linda K; Peggs, Richard L  
Subject: RE: 64CSR43 FOOD MANUFACTURING FACILITIES - Comments

Ann,

I thought this was addressed in the fees for permit rule. Dairy Farms, milk plants, etc. were exempted by the definition in 64CSR51. This is something that Phil Jones had wanted. I want to make sure that the facilities in 64CSR43 are required to be inspected and permitted. The fee exemption should be in 64CSR51...is this not correct? We also added the Dept. of Ag. exemption in 64CSR43 just to make sure.

Brad Cochran, R.S.  
Director  
OEHS-Public Health Sanitation Division  
350 Capitol Street, Room 313  
Charleston, WV 25301-3713  
Phone:(304)-558-6730  
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E-mail: [Brad.J.Cochran@wv.gov](mailto:Brad.J.Cochran@wv.gov)

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From: Peggs, Richard L  
Sent: Thu 6/24/2010 11:32 AM  
To: Goldberg, Ann A; Whaley, Linda K; Cochran, Brad J  
Subject: RE: 64CSR43 FOOD MANUFACTURING FACILITIES - Comments

I don't want fees required from BPH dairy facilities that already pay fees to AG. Whatever would be the proper exemption to accomplish this is fine with me.

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From: Goldberg, Ann A  
Sent: Thursday, June 24, 2010 11:27 AM

**To:** Whaley, Linda K; Peggs, Richard L; Cochran, Brad J  
**Subject:** RE: 64CSR43 FOOD MANUFACTURING FACILITIES - Comments

Linda,

More to the point. This rule, 64CSR43, in section 2.3. the definition of a "Food Manufacturing Facility" specifically does not include facilities regulated by WV Dept of Ag.

Richard, does this address your concern?  
Ann

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**From:** Whaley, Linda K  
**Sent:** Thursday, June 24, 2010 11:20 AM  
**To:** Peggs, Richard L; Cochran, Brad J; Goldberg, Ann A  
**Subject:** RE: 64CSR43 FOOD MANUFACTURING FACILITIES - Comments

64CSR51 Fees for Services Rule

3.24. Food Manufacturing Facility -- Any building or group of buildings that manufactures, processes, or packs food for human consumption. This term does not include farms, restaurants or other retail food establishments where food is prepared and served directly to consumers or facilities regulated by the Department of Health and Human Resources rule Grade "A" Pasteurized Milk, 64CSR34.

I think it would be redundant to include this in the Food Manufacturing Rule, but something to this effect could be added if necessary.

Linda

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**From:** Peggs, Richard L  
**Sent:** Thursday, June 24, 2010 9:47 AM  
**To:** Cochran, Brad J; Goldberg, Ann A  
**Cc:** Whaley, Linda K  
**Subject:** 64CSR43 FOOD MANUFACTURING FACILITIES - Comments

Presently the Department of Agriculture requires annual regulatory permit fees from facilities (\$75.00/facility) that process milk and milk related products, which includes dairy pasteurization plants, cheese manufacturing plants and ice cream plants. At this time WV BPH permits one (1) ice cream plant , two (2) fluid milk pasteurization plants, one of which also manufactures fresh goat cheese and one (1) aged raw milk cheese facility. WV BPH will also permit an additional three (3) cheese manufacturing facilities in the near future. Since these facilities pay an annual permit fee to the WV AG, are these dairy related facilities going to be required to submit an annual fee to the WV BPH? If not, should language in the proposed regulation reflect this policy?

Richard L. Peggs, M.S., R.S.  
Program Manager, Grade "A" Milk Program  
Public Health Sanitation Division  
Office of Environmental Health Services  
350 Capitol Street, Room 313  
Charleston, West Virginia 25301-3713  
Phone: 304-558-9150  
Fax: 304-558-1071  
Cell: 304-550-5610

2010/6/27

**Goldberg, Ann A**

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**From:** marlapisciotta@frontier.com  
**Sent:** Sunday, June 27, 2010 10:36 AM  
**To:** Goldberg, Ann A  
**Subject:** food sanitation

Good morning,

Could you tell me if the "new" food sanitation proposal will impact such things as dinners being served at churches and by organizations or places that have cookoffs for competition such as chili?

Also, in Hampshire County we have a farmers market. Will this new rule have an impact in any way on that?

Thanks so much

*[Faint signature]*

2010 SR43

**Goldberg, Ann A**

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**From:** Cochran, Brad J  
**Sent:** Monday, June 28, 2010 11:34 AM  
**To:** 'marlapisciotta@frontier.com'  
**Cc:** Goldberg, Ann A  
**Subject:** Food Sanitation

Response to Comment #2

Marla,

Your concerns regarding a "new" food sanitation rule has been referred to me for response. I assume you are referring to the proposed food manufacturer rule.

[REDACTED] only deals with establishments who manufacture food and [REDACTED] have any [REDACTED] (chili-cook-offs and farmers markets). Church dinners would not be impacted as well.

We have published a Farmers Market Vendor Guide which can be viewed at the following website:

<http://www.wvdhhr.org/phs/food/Farmers%20Market%20Vendors%20Guide%20FINAL%20with%20cover.pdf>

If you are a food manufacturer who sells product at a farmers market, only your facility would be subject to the new rule.

I hope this answers your questions.

**Brad**

Brad Cochran, R.S.  
Director  
OEHS-Public Health Sanitation Division  
350 Capitol Street; Room 313  
Charleston, WV 25301-3713

Phone:(304)558-6730  
Fax:(304)558-1071  
E-mail: [Brad.J.Cochran@wv.gov](mailto:Brad.J.Cochran@wv.gov)

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

FILED

2010 JUL 29 AM 11:29

SERIES 43  
FOOD MANUFACTURING FACILITIES

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 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. 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.