



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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

AGENCY: Health TITLE-SERIES: 64-106
RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No
RULE NAME: 64-106 Home-Based Food Production

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 16-1-4b2,5,8; 16-1-6m; 16-1-11

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:

STATUTORY AUTHORITY

The Secretary of the Department of Health and Human Resources shall propose rules for legislative approval in accordance with W. Va. Code §29A-3-1 et seq. to implement the all of the provisions of W. Va. Code § 16-1-4b2,5,8; 16-1-6m; 16-1-11. The Department of Health and Human Resources is empowered to enact each provision of W. Va. Code of State Rules 64-17 by the authority specifically found in W. Va. Code § 64-106.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/27/2017

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/27/2017

COMMENTS RECEIVED: Yes

(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?

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

Brief Summary of Rule: This rule establishes the requirements governing home-based food production operation permits. The new rule applies to persons, operating out of the persons dwelling, who prepare, process, package, store, and distribute, acidified food products or frozen fruits and vegetables, for sale directly other at a farmers market within the state. The rule creates an exception to Food Manufacturing Facilities Rule W.Va. Code R. 64-43-1 et seq. The provisions of this rule constitute an express exclusion from the provisions of the Food Manufacturing Facilities Rule (W.Va. Code R. 64-43-1 et seq.) and a person authorized by the Bureau to prepare, process, package, store, and distribute, acidified food products or frozen fruits and vegetables for sale at a farmers market is expressly exempt from compliance with the provisions of Food Manufacturing Facilities Rule.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Statement of Circumstances:

During the previous two regular legislative sessions, bills have been introduced to permit persons to sell potentially harmful food products produced in their home kitchen at farmers markets -- SB 434 (Allowing home-based micro-processed foods sold at farmers markets) (2016) and SB 27 (Relating to microprocessor permit) (2017). During the 2016 regular legislative session, SB 434 passed the Senate but it was not taken up by the House of Delegates. During the 2017 regular legislative session, both the House and Senate each passed different versions SB 27, but were unable to reach an agreement on the provisions of the bill prior to the expiration of the regular session on April 8, 2017.

Both bills would have permitted persons to can or preserve low-acid foods such as green beans, ramps and tomatoes in their home kitchens and then sell their food products at farmers markets and similar events. The legislation was intended to allow farmers to produce food items in their own home kitchen with fresh products grown on their farms, but which they were not able to sell at a farmers market. The bills encourage food preservation while also giving small farmers another way to sell produce grown on their farms.

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

This rule applies to persons, operating out of the persons dwelling, who prepare, process, package, store, and distribute, acidified food products or frozen fruits and vegetables, for sale directly to a person only at a farmers market within the state. Additionally, it creates an express exclusion from the provisions of the Food Manufacturing Facilities Rule (W.Va. Code R. 64-43-1 et seq.) and a person authorized by the Bureau to prepare, process, package, store, and distribute, acidified food products or frozen fruits and vegetables for sale at a farmers market is expressly exempt from compliance with the provisions of W.Va. Code R. 64-43-1 et seq.

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

This rule applies to persons, operating out of the persons dwelling, who prepare, process, package, store, and distribute, acidified food products or frozen fruits and vegetables, for sale directly to a person only at a farmers market within the state. Additionally, it creates an express exclusion from the provisions of the Food Manufacturing Facilities Rule (W.Va. Code R. 64-43-1 et seq.) and a person authorized by the Bureau to prepare, process, package, store, and distribute, acidified food products or

frozen fruits and vegetables for sale at a farmers market is expressly exempt from compliance with the provisions of W.Va. Code R. 64-43-1 et seq.

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2017 Increase/Decrease (use "-")	2018 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost		49,331.00	10,188.00
Personal Services		35,388.00	9,635.00
Current Expenses		13,943.00	553.00
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues		350.00	350.00

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

This rule will require Public Health Sanitation staff to provide training related to the requirements of the rule for anyone that wishes to become a microprocessor. Expense will include creating a new module for the Environmental Health Reporting System and inspection forms. Printing of informational reference packets to be distributed to the permitted home based microprocessors. Travel expenses to provide assistance to the microprocessors, inspections and training. It is estimated that there will be ten microprocessors at a fee of \$35 will generate income of \$350.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

TITLE 64

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

SERIES 106
HOME-BASED FOOD PRODUCTION

64-106-1. General.

1.1. Scope. -- This rule establishes the requirements governing home-based food production operation permits.

1.2. Authority. -- W.Va. Code § 16-1-4(b)(2), (5) & (8), W.Va. Code § 16-1-6(m), W.Va. Code § 16-1-11, and W.Va. Code §§ 16-7-1 et. seq.

1.3. Filing Date. --

1.4. Effective Date. --

1.5 Sunset Provision. -- This rule shall terminate and have no further force or effect upon the expiration of 5 years from its effective date.

1.6. Applicability. -- This rule applies to persons, operating out of the person's dwelling, who prepare, process, package, store, and distribute, acidified food products or time/temperature control for safety food, for sale directly to a person only at a farmers market within the state.

1.7. Exception to Food Manufacturing Facilities Rule. -- The provisions of this rule constitute an express exclusion from the provisions of the Food Manufacturing Facilities Rule (W.Va. Code R. 64-43-1 et seq.) and a person authorized by the Bureau to prepare, process, package, store, and distribute, acidified food products or time/temperature for safety food for sale at a farmers market is expressly exempt from compliance with the provisions of W.Va. Code R. 64-43-1 et seq.

64-106-2. Definitions.

2.1. "Acid foods" means foods that have a natural pH of 4.6 or below.

2.2 "Acidified foods product" means 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, and foods that are stored, distributed, and retailed under

refrigeration are excluded from the coverage of this rule series.

2.3. "Commissioner" means the Commissioner of the Bureau for Public Health or his or her lawful designee.

2.4. "Consignment farmers market" means a market in which two or more persons deliver their own farm and food products to a common location maintained by a third party that markets the vendors' products and receives a percentage share of the profits from sales, with the individual vendor retaining ownership of the farm and food product until it is sold. Consignment farmers markets offering for sale time/temperature control for safety foods are regulated by 64 CSR 17 (Food Establishments Rule).

2.5. "Farmers market" means:

2.5.a. A traditional farmers market;

2.5.b. An on-farm market or farm stand; or

2.5.c. A consignment farmers market.

2.6. "Home-based food production operation", "operator", or "operation" means an individual, operating out of the individual's dwelling, who prepares, processes, packages, stores, and distributes acidified food product or time/temperature for safety foods, for sale directly to a person at a farmers' market.

2.7. "Local health department" means a health department serving one or more counties or one or more municipalities or a combination thereof.

2.8. "Local Health Officer" means the executive officer of the local board of health or his or her lawful representative.

2.9. "On-farm market or farm stand" means an individual producer that sells farm and food products at his/her farm.

2.10. "Person" means an individual, partnership, association, syndicate, company, firm, trust, corporation, institution, department, division, bureau, agency, or any entity recognized by law.

2.11. "pH" means the measurement of the acidity or alkalinity of a solution commonly measured on a scale of 0 to 14.

2.12. "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 food products.

2.13. "Time/temperature control for safety food" or "TCS" means any food that consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustaceans, or other ingredients which is in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms, or any food that requires temperature control for safety. "Time/temperature control for

safety food” includes:

2.13.a. An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts; cut melons; cut leafy greens; cut tomatoes or mixtures of cut tomatoes not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

2.13.b. Certain foods that are designated as Product Assessment Required (PA) because of the interaction of the pH and Aw values in these foods. Below is a table indicating the interaction of pH and Aw for control of spores in food heat treated to destroy vegetative cells and subsequently packaged:

	Aw	values	pH values	
		4.6 or less	>4.6--5.6	>5.6
(1)	<0.92	non-TCS	non-TCS	non-TCS
(2)	>0.92--0.95	non-TCS	non-TCS	PA
(3)	>0.95	non-TCS	PA	PA

Note: Foods in item (2) above with a pH value greater than 5.6 and foods in item (3) above with a pH value greater than 4.6 are considered potentially hazardous unless a product assessment (PA) is conducted pursuant to the 2013 Federal Drug Administration Food Code.

2.14. “Traditional farmers market” means a farmers market where two or more vendors gather to sell farm and food products directly to the consumer at a fixed location.

2.15. “Water activity” or “Aw” means the water activity of a food or the ratio between the vapor pressure of the food itself, when in a completely undisturbed balance with the surrounding air media, and the vapor pressure of distilled water under identical conditions.

64-106-3. Home-Based Food Production Operation Permits.

3.1. The operator of a home-based food production operation must have a valid permit issued by the Commissioner.

3.2. To be eligible for a home-based food production operation permit the applicant shall:

3.2.a. Successfully complete either:

3.2.a.1. The Better Control Process School training for acidified food products; or

3.2.a.2. A West Virginia University Extension Service program approved by the Commissioner.

3.2.b. Possess a valid food handler’s permit from the local health department, if applicable; and

3.2.c. Use a USDA or process authority pre-approved and tested recipe: provided that any acidified food product recipe must have an finished equilibrium pH of 4.0 or below and heat treatment.

3.3. A permittee may only sell or offer to sell at a farmers market directly to a person for his own use and not for resale;

3.4. A permittee may not sell, or offer to sell, food items:

3.4.a. At wholesale; or

3.4.b. Via the Internet or interstate commerce.

3.5. A permittee must source 70% percent of any produce for a recipe from farm or garden owned by the applicant and gross receipts from the sale of food may not exceed \$7,500 in a calendar year.

64-106-4. Application.

4.1. A person must apply for a home-based food production operation permit with the Commissioner in writing on a form prescribed by the Commissioner, together with a fee of \$35.

4.2. The application must include the following information:

4.2.a. The applicant's name, mailing address, physical location of home-based food production operation, telephone number, and email address, if available;

4.2.b. The food products the applicant intends to offer for sale along with evidence that the food products will be produced in conformance with a USDA or West Virginia University pre-approved and tested recipe;

4.2.c. Evidence of the successful completion of a training program provided in Subdivision 3.2.a.;

4.2.d. Evidence of a valid food handler's permit from the local health department in the county in which home-based food production will occur, if applicable; and

4.2.e. The signature of the applicant or his or her authorized representative.

4.3. The application, a properly approved recipe, and applicable permit fee must be submitted for approval at least fifteen (15) days prior to the applicant operating a home-based food production operation.

4.4. Only applications that are complete will be considered. In order to be considered complete, an application must include:

4.4.a. All of the information requested by the application;

4.4.b. The applicable permit fee; and

4.4.c. The signature of the applicant or his or her authorized representative.

4.5. The applicant may submit such additional documents or information as the applicant considers

relevant to the application and compliance with the provisions of this rule series.

4.6. In the event that an application is determined to be incomplete, the Commissioner will notify the applicant of the information necessary to complete the application within 10 days of his or her receipt of the application, and retain the application submitted pending receipt of the additional information.

4.7. *Permit Issuance.* The Commissioner will issue a permit to an applicant who intends to operate a home-based food production operation upon the submission of a complete application that contains all of the information required in subsection 4.1 and upon an inspection pursuant to section 6 by the Commissioner to ensure compliance with the provisions of this rule series.

4.7.a. The operator of a home-based food production operation permit must make the permit available for inspection by a local health officer upon request.

4.7.b. A permit expires at midnight on the 31st day of December following the date of issuance.

4.7.c. A permit is not transferable or assignable and automatically becomes invalid upon a change of ownership or upon suspension of the permit.

4.8. The Commissioner will notify the local health department of the county in which the home-based food production operation is situated upon issuance of a permit.

4.9. Any changes in the types of food products the permittee intends to offer for sale must be submitted to the Commissioner for prior approval.

4.10. A permit is subject to unannounced on-site periodic review by the Commissioner.

64-106-5. Denial, Suspension, or Revocation.

5.1 The Commissioner may deny approval of a home-based food production operation permit for failure to meet the provisions of this rule series. If the Commissioner determines to deny approval of a permit, the Commissioner will notify the applicant by a notice identifying the reasons for the determination. The notice will be delivered in person, or by either registered or certified mail.

5.2. The Commissioner may suspend a home-based food production operation permit for failure to meet provisions of this rule series. If the Commissioner determines that it is necessary to suspend a permit, the Commissioner will notify the applicant or operator by a written notice identifying the reasons for the determination. The notice will be delivered in person or by either registered or certified mail.

5.3. The Commissioner may revoke a home-based food production operation permit for repeated or serious violations of any of the provisions of this rule series or for interference with the Commissioner or a local health officer in the performance of his or her duties. If the Commissioner determines to revoke a permit, the Commissioner will notify the operator of a home-based food production operation by a written notice identifying the reasons for the determination. The notice will be delivered in person or by either registered or certified mail.

5.4. Upon the suspension or revocation of a permit, the Commissioner will notify the local health department of the county in which the home-based food production operation is situated.

5.5. A denial, suspension or revocation will become final 30 days after the delivery of the notice of denial, suspension or revocation notice unless the applicant or operator, within that 30-day period, gives written notice of a request for a hearing. Hearings will be conducted in accordance with the Administrative Procedure Act (*W.Va. Code §§ 29A-5-1 et. seq.*), and the Bureau for Public Health rule series, Rules of Procedure for Contested Case Hearings and Declaratory Rulings (*W.Va. Code R. §§ 64-1-1 et seq.*).

5.6. The Commissioner will not approve or reinstate a home-based food production operation permit until he or she determines by an inspection that the operator of a home-based food production operation is in compliance with all applicable provisions of this rule and any orders, rules or instructions issued by the Commissioner or local health officer.

64-102-6. Inspections.

6.1. The Commissioner will inspect a home-based food production operation to determine satisfactory compliance with the provisions of this rule series or any orders, notices, instructions or specifications issued pursuant to this rule, prior to the issuance of a permit and at least once per permit year while processing approved product(s).

6.2. The Commissioner may make as many additional inspections as necessary to determine satisfactory compliance with the provisions of this rule series or any orders, notices, instructions or specifications issued pursuant to this rule series.

6.3. A local health department may inspect a home-based food production operation to investigate a food item that may be deemed to be adulterated or an outbreak or suspected outbreak of illness known or suspected to be caused by a contaminated food item. The home-based food production operation shall cooperate with the local health department in any such inspection. If, as a result of such inspection, the local health department determines that the home-based food production operation has produced an adulterated food item or was the source of an outbreak of illness caused by a contaminated food item, the local health department may charge and collect from the home-based food production operation a fee in an amount that does not exceed the actual cost of the local health department to conduct the investigation.

6.4. The local health department will coordinate any inspection or investigation of a home-based food production operation with the West Virginia Bureau for Public Health, Office of Environmental Health Services. Any recall or embargo of a home-based food production product shall follow guidance by the West Virginia Bureau for Public Health.

64-106-7. Operational Requirements.

7.1. The operator of the home-based food production operation must take all reasonable steps to protect food items intended for sale from contamination while preparing, processing, packaging, storing, and distributing the items, including, but not limited to:

7.1.a. Maintaining direct supervision of any person, other than the operator, engaged in the

processing, preparing, packaging, or handling of food intended for sale;

7.1.b. Prohibiting all animals, including pets, from entering the area in the dwelling in which the home-based food production operation is located while food items are being prepared, processed, or packaged and prohibiting these animals from having access to or coming in contact with stored food items and food items being assembled for distribution;

7.1.c. Prohibiting all domestic activities in the kitchen while the home-based food production operation is processing, preparing, packaging, or handling food intended for sale;

7.1.d. Prohibiting any person who is infected with a communicable disease that can be transmitted by food, who is a carrier of organisms that can cause a communicable disease that can be transmitted by food, who has an infected wound, or who has an acute respiratory infection from processing, preparing, packaging, or handling food intended for sale by the home-based food production operation;

7.1.e. Prohibiting any person from smoking in the portion of a home used for the preparation, packaging, storage, or handling of food products and related ingredients or equipment, or both, while food products are being prepared, packaged, stored, or handled;

7.1.f. Ensuring that all people engaged in processing, preparing, packaging, or handling food intended for sale by the home-based food production operation are knowledgeable of and follow safe food handling practices;

7.1.g. Ensuring all food surfaces that come in contact with food are cleaned and sanitized including but not limited to equipment, utensils, sinks, and countertops prior to being used for home-based food production;

7.1.h. Ensuring that the equilibrium pH and temperature is observed for each batch of acidified food product produced. Equilibrium pH must be monitored by a pH meter, and temperature monitored by a food thermometer. Both the pH meter and thermometer must be calibrated following the manufacturer's instructions, at a minimum, once per day or once per shift.

7.1.i. Ensuring that all containers used for home based food production are inspected for any defects prior to and after products are placed into the containers. Any containers with defects may not be used for home based food production. Containers that have defects or that fail to seal properly may not be sold to the public.

7.2. Each home-based food production operation shall maintain a clean and sanitary facility to produce approved products including, but not limited to:

7.2.a. An approved water supply;

7.2.b. A separate storage place for ingredients used in foods and finished food products intended for sale;

7.2.c. A properly functioning refrigeration unit maintaining food temperatures of 41°F or below;

7.2.d. Adequate facilities, including a sink with an adequate hot water supply to meet the demand for the cleaning and sanitization of all utensils and equipment;

7.2.e. Adequate facilities for the storage of utensils and equipment;

7.2.f. Adequate hand washing facilities;

7.2.g. A properly functioning toilet facility;

7.2.h. No evidence of insect or rodent activity; and

7.2.i. An approved sewage disposal system, either onsite treatment or publicly provided.

7.3. A home-based food production operation that produces an acidified food product, must have an operational and calibrated pH meter.

64-106-8. Packaging Requirements.

8.1. All food items packaged at the operation for sale must be properly labeled.

8.2 Food items to be frozen may not use the reduce oxygen or "vacuum sealing" method of packaging.

8.3. The label must comply with federal laws and regulations and must include:

8.3.a. The name and address of the home-based food production operation;

8.3.b. The common or usual name of the product being sold;

8.3.c. The ingredients used to make the product in descending order of predominance by weight;

8.3.d. The net weight of the contents of the package or container;

8.3.e. A declaration if the product includes a major food allergen, including, but not limited to, milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts and /or soybeans;

8.3.f. A conspicuous statement printed in all capital letters, 12-point type or larger, and in a color that provides a clear contrast to the background that reads: "NOT FOR RESALE--PROCESSED AND PREPARED BY A HOME-BASED FOOD PRODUCTION OPERATION THAT IS NOT SUBJECT TO WEST VIRGINIA'S FOOD SAFETY RULES"; and

8.4. Each container must be marked with the date and batch prepared in a home-based food production operation

64-106-9. Records.

9.1 Records shall be maintained by operator to identify the distribution of food products to facilitate,

when necessary, the segregation of specific food batches that may have become contaminated or otherwise rendered unfit for human consumption.

9.2. The operator shall maintain records that include:

9.2.a. The identify of each food product that is produced by the common or usual name of the food product;

9.2.b. A list of all ingredients of the food product, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight shown with common or usual names, the purchase date, purchase location, product brand, lot or UPC number and any date indicated on the package; and

9.2.c. All ingredients and quantity sourced from the operator's own farm or garden.

9.2.d. The date on which the food product was packaged, the net quantity of the food product separated by batch; and

9.2.e. Any deviations in a batch of produced food product.

9.3. In addition to the records required to be maintained by subsection 9.2, an operator that produces an acidified food product shall maintain the following records:

9.3.a. Finished product equilibrium pH and temperature for each batch of acidified food product; and

9.3.b. Proper calibration of the pH meter and thermometer pursuant to subdivision 7.1.h.

9.5. Copies of all records provided for in this section shall be retained by the operator for a period of not less than three years from the date of production, on forms approved by the Commissioner.

64-106-10. Enforcement.

Whenever the Commissioner finds that a food product prepared in a home-based food production operation is, by reason of microbiological, physical, chemical or allergenic contamination, injurious to the public health, the Commissioner may prohibit the sale of such food until the home-based food production operation in which it was prepared is inspected and found to be in substantial compliance with the with the provisions of this rule series or any orders, notices, instructions or specifications issued pursuant to this rule series, and the contamination is eliminated.