



WEST VIRGINIA SECRETARY OF STATE

KRIS WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Agriculture

RULE TYPE: Legislative

TITLE-SERIES: 61-42

RULE NAME: Cottage Foods-Homemade Potentially
Hazardous Food Items

CITE AUTHORITY: §19-40-4

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

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

Yes

Amie J Minor -- 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 61
LEGISLATIVE RULE
WEST VIRGINIA DEPARTMENT OF AGRICULTURE

SERIES 42
COTTAGE FOODS-HOMEMADE POTENTIALLY HAZARDOUS FOOD ITEMS

§61-42-1. General.

1.1. Scope. -- This legislative rule establishes the framework for regulation of the sale of homemade potentially hazardous food items, including permitting, inspection, labeling, and exemptions for potentially hazardous homemade cottage food.

1.2. Authority. -- W. Va. Code §19-40-4.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on August 1, 2032.

§61-42-2. Incorporated by Reference.

2.1. The Homemade Food Items – Cottage Food Vendor Guide, published by the West Virginia Department of Agriculture, is hereby incorporated by reference.

2.2. Regulatory Guidance for Best Practices, Cottage Foods, published by the Association of Food and Drug Officials, is hereby incorporated by reference.

§61-42-3. Definitions.

3.1. “Acidified foods” means low-acid foods to which acid or acid foods are added with a water activity of greater than 0.85 and a finished equilibrium of pH 4.6 or below. Acidified foods are considered potentially hazardous foods.

3.2. “Commercial kitchen” means a permitted food manufacturing facility designed for food production and food safety and eligible for interstate commerce.

3.3. “Commissioner” means the Commissioner of the West Virginia Department of Agriculture.

3.4. “Community kitchen” means a kitchen that is used by community members for preparing foods, and is considered a non-permitted kitchen.

3.5. “Cottage food” means a homemade food item intended for human consumption that is produced and, if packaged, packaged at the residential property of the producer and sold directly to a consumer. The term includes non-potentially hazardous and potentially hazardous foods, but excludes meat, meat products, poultry, seafood, and Grade A dairy products.

3.6. "Cottage food vendor" means a home-based permitted business producing and selling cottage foods.

3.7. "Delivered" means transferred to the consumer, either immediately upon sale or at a time thereafter.

3.8. "Farm kitchen" means an on-premises food preparation facility manufacturing items for sale from a cottage food vendor for direct consumer purchase and is considered a non-permitted kitchen.

3.9. "Farm kitchen" means an on-premises food preparation facility manufacturing items for sale at a qualified cottage food for direct consumer purchase and is considered a non-permitted kitchen.

3.10. "Fermented products" means food processed through the conversion of carbohydrates to alcohol or organic acids using microorganisms under anaerobic conditions.

3.11. "Fermented products" means food processed through the conversion of carbohydrates to alcohol or organic acids using microorganisms under anaerobic conditions.

3.12. "Freeze-dried" means that food has been subjected to a process in which water is removed from a product after it is frozen and placed under a vacuum, allowing the ice to change directly from a solid phase to a vapor. The freeze-drying process consists of three separate processes: freezing, primary drying, and secondary drying.

3.13. "Kitchen" means a room or area in which food is prepared, produced, packaged, or cooked.

3.14. "Label" means a panel or panels found on a packaged food item.

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

3.16. "Low-acid canned food" means any food (other than alcoholic beverages) with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85, excluding tomatoes and tomato products having a finished equilibrium pH less than 4.7.

3.17. "Non-potentially hazardous cottage food" means a food item that does not require time/temperature controls for safety to limit pathogenic microorganism growth or toxin formation.

3.18. "Pickled product" means a food product that has been processed for preservation either through an anaerobic fermentation in brine or immersion in vinegar.

3.19. "Potentially hazardous cottage food" means any food item that requires time/temperature control or other protocols for safety to limit pathogenic microorganism growth or toxin formation.

3.20. "Potentially hazardous cottage food vendor permit" means a permit which allows potentially hazardous cottage foods to be produced and sold.

3.21. "Process authority" or "Process control authority" means a person who has been recognized by the Association of Food and Drug Officials as having 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 and is found in the food processing authorities directory.

3.22. "Sanitize" means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

3.23. "Uncut produce" means fruits and vegetables that have not been cut beyond field harvest and are offered for sale as a whole item.

3.24. "WVDA" or "the Department" means the West Virginia Department of Agriculture.

§61-42-4. Potentially Hazardous Cottage Food Vendor Permits.

4.1 All potentially hazardous cottage food vendors shall apply for a potentially hazardous cottage food vendor permit from the WVDA on a form provided by the Commissioner.

4.2. Potentially hazardous cottage food vendor permits are effective from January 1 through December 31 of each year.

4.3. A potentially hazardous cottage food vendor permit, once issued, is valid in all counties in this state. A cottage food produced pursuant to the provisions of this rule shall be sold only within the geographic boundaries of the State of West Virginia.

4.4. A potentially hazardous cottage food vendor permittee is not required to obtain a food establishment permit to sell from home.

4.5. If a potentially hazardous cottage food vendor already holds a WVDA-issued farmers market vendor permit, the farmers market vendor permit may be submitted to WVDA as the required documentation for a potentially hazardous cottage food vendor permit. Only foods approved under the farmers market vendor permit shall be authorized for sale by the potentially hazardous cottage food vendor.

4.6. Separate WVDA-issued farmers market vendor permits remain required for the sale by any person of potentially hazardous foods at farmers markets.

§61-42-5. Permitted and Prohibited Cottage Food Sales.

5.1. All non-potentially hazardous food products may be sold at home as cottage foods without a cottage food vendor permit, in accord with W. Va. Code §19-35-6 and §19-40-6. Such sales are otherwise not subject to the provisions of this rule.

5.2. The following potentially hazardous cottage food products may be sold at home if a potentially hazardous cottage food vendor permit has been obtained:

5.2.1. Canned acidified foods, including, but not limited to:

5.2.1.a. Pickled products;

5.2.1.b. Sauces, such as hot sauce, marinara, or spaghetti sauce;

5.2.1.c. Salsas;

5.2.1.d. Fermented products;

5.2.1.e. Acidified fruits and vegetables;

5.2.1.f. Acidified condiments; and

5.2.1.g. Non-standardized jams and jellies;

5.2.2. Cut produce;

5.2.3. All cottage food products that are required to be time or temperature controlled or employ other protocols for safety to limit pathogenic microorganism growth or toxin formation; and

5.2.4. Any potentially hazardous freeze-dried foods.

5.3. The following food products are not permitted to be sold at home as cottage foods, regardless of whether a potentially hazardous cottage food vendor permit has been obtained:

5.3.1. Wild-harvested mushrooms;

5.3.2. Sprouted seeds; and

5.3.3. Meat, meat products, poultry, poultry products, seafood, or Grade A dairy products.

§61-42-6. Labeling.

6.1. All potentially hazardous cottage food products made or packaged in West Virginia for direct, non-wholesale, purchase by consumers – whether made in a commercial kitchen inspected by the West Virginia Bureau for Public Health or local health departments under its jurisdiction, or made in a non-commercial home, farm, or community kitchen – shall carry product labels.

6.2. Labeling shall generally conform to U.S. Food and Drug Administration rules and guidance unless specifically noted.

6.3. Required label elements shall be of a size and style that is easily legible to the average person and shall consist of:

6.3.1. Statement of identity, which is the common name of the product;

6.3.2. Company name of producer, packer, or distributor. Unless the name given is the actual producer, the name must be accompanied by a statement noting the relation to the product;

6.3.3. City, state and zip code of the producer, packer, or distributor;

6.3.4. Ingredients listed in descending order from greatest weight to least. Single ingredient products shall include an ingredient list to ensure consumers that it is the only ingredient in the product. The ingredient list shall begin with "Ingredients:" followed by the list;

6.3.5. Net contents or numerical count located in bottom third of the primary label panel in standard U.S. measures, followed by the metric equivalent in parentheses. Honey shall be measured by weight. Syrups shall be measured by liquid volume;

6.3.6. A statement of any of the major food allergens contained in the product, as specified by U.S. Food and Drug Administration. The statement shall be placed directly below the ingredient list and shall begin with "Contains" followed by the allergens. The current allergens are milk, egg, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame. Products that contain tree nuts, fish, or crustacean shellfish must also declare the specific type of allergen in parentheses following the broader category of allergen;

6.3.7. Safe handling instructions such as freezing or refrigeration requirements and minimum safe heating temperatures when applicable;

6.3.8. Any date or lot codes that are required elsewhere in these rules for potentially hazardous foods; and

6.3.9. The following statement: "This product was made in a non-commercial or home kitchen that may not be subject to inspection and may contain cross-contact allergens not included in the allergen statement."

6.4. All potentially hazardous cottage food producers shall submit product labels and any associated forms to WVDA for review.

§61-42-7. Requirements For the Sale of Potentially Hazardous Cottage Foods.

7.1. A producer of canned acidified foods must satisfy the following requirements:

7.1.1. The producer must have the process for preparing and preserving the products approved by a process control authority recognized by WVDA prior to selling the products. The process approval must be obtained in a manner approved by the WVDA, as provided in the West Virginia Cottage Food Vendor Guide;

7.1.2. The producer must keep records to demonstrate the source of the produce and all other ingredients in the producer's canned acidified foods. Recordkeeping shall include, but not be limited to:

7.1.2.a. Name of product;

7.1.2.b. Number of units prepared;

7.1.2.c. Record of raw ingredients used and vendor from which ingredients were sourced;

7.1.2.d. Date/Lot code; and

7.1.2.e. Where product/lot was distributed.

7.1.3. If the producer has a private water supply, he or she must have the water supply tested prior to permitting and at least annually thereafter and demonstrate through a written record of testing for coliform bacteria to signify that the water supply is potable. The WVDA may require more frequent testing, or additional testing, if circumstances dictate that such testing is necessary to ensure food safety.

7.1.3.a. Maximum coliform levels shall be <1cfu/100mL.

7.1.3.b. For municipal water sources, a certificate of testing must be available for review and the person utilizing the kitchen for preparation of potentially hazardous foods should verify use during potentially hazardous food production if more than one water source is present.

7.1.3.c. WVDA may establish additional water quality standards in order to meet state water quality guidelines.

7.1.4. The producer must submit proof of having completed Better Process Control School or other higher-level food safety training, as defined in subsection 7.4 of this rule.

7.2. A seller of the following potentially hazardous cottage foods must obtain a cottage food vendor permit from the Department. To be eligible for a vendor permit, the applicant must submit proof of holding a Food Handler's Card or having completed other higher-level food safety training, as defined in subsection 7.4 of this rule:

7.2.1. Cut produce;

7.2.2. Baked goods that require time and temperature control;

7.2.3. Infused foods, such as honeys or syrups that have additional flavors or ingredients added;

7.2.4. Condiments; and

7.2.5. All other potentially hazardous foods.

7.3. A seller of potentially hazardous cottage foods prepared in a facility that is inspected or certified by the Federal Food and Drug Administration (FDA), USDA, the West Virginia Bureau for Public Health, or a local health department, that has been issued a Food Manufacturing Permit by the Bureau for Public Health must obtain a vendor permit from the Department to sell potentially hazardous cottage foods. To be eligible for a vendor permit, the applicant must submit proof of inspection or certification by FDA or USDA or a copy of the Food Manufacturing Permit with his or her vendor permit application.

7.4. People engaged in the production of any of the potentially hazardous cottage foods identified in this rule shall attend and keep current one or more of the following WVDA-approved food-safety courses, and shall provide documentation of successful completion of the scope of curriculum:

7.4.1. ServSafe Food Handler Course offered by the National Restaurant Association;

7.4.2. Better Process Control School;

7.4.3. Acidified Foods Manufacturing School;

7.4.4. Good manufacturing practices (GMP) certificate program; or

7.4.5. Other curriculum approved by WVDA.

7.5. A home, community, farm, or commercial kitchen may be used by a potentially hazardous cottage food vendor. The WVDA reserves the right to limit the preparation and preservation of a particular potentially hazardous cottage food to a certain type of kitchen to ensure food safety.

7.6. A potentially hazardous cottage food vendor permit shall state what products the vendor permit covers. Only those products that have been approved by WVDA may be sold by the holder of a cottage food vendor permit.

§61-42-8. Inspections of Potentially Hazardous Cottage Food Kitchens.

8.1. Kitchen inspections for potentially hazardous cottage food vendors shall be conducted by a WVDA representative upon the initial permit application and following the annual permit renewal. Non-compliance violations may result in additional inspections.

8.2. Potentially hazardous cottage food vendors will be charged \$27 per hour, excluding travel hours, for inspections, which will be billed directly to the potentially hazardous cottage food vendor. Fees may be prorated as applicable.

8.2.1. Inspection costs will be assessed for both the annual inspection and any follow-up inspections after a violation has occurred.

8.3. During a kitchen inspection, WVDA will minimally inspect to ensure the following:

8.3.1. That only the specific foods identified on the potentially hazardous cottage food vendor permit are being produced in the kitchen during the time of production of those foods;

8.3.2. That the permitted food operation understands that no person other than the vendor permit holder, or a person under his or her direct supervision, may be engaged in the processing, preparing, packaging, or handling of any potentially hazardous food products or be in the home kitchen during the preparation, packaging, or handling of any potentially hazardous food products;

8.3.3. That no preparation, packaging, or handling of potentially hazardous food products is occurring in the home kitchen concurrent with any other domestic activities, such as home meal

preparation, dishwashing, clothes washing or ironing, kitchen cleaning, or guest entertainment. Preparation activities and routine home activities must be clearly separated by time;

8.3.4. That no infants, small children, or pets are in the home kitchen during the preparation, packaging, or handling of any potentially hazardous food products;

8.3.5. That kitchen equipment and utensils being used to produce food products can be properly cleaned and sanitized;

8.3.6. That all food contact surfaces, equipment, and utensils used for the preparation, packaging, or handling of any potentially hazardous food products are washed, rinsed, and sanitized before each use;

8.3.7. That all food, food preparation equipment, and storage areas are free of rodents and insects; and

8.3.8. That no persons involved in the preparation, packaging, or handling of potentially hazardous cottage foods:

8.3.8.a. Are working with exposed food, cleaning equipment, utensils, linens, or unwrapped single-service or single-use articles while experiencing any of the following symptoms:

8.3.8.a.1. Vomiting;

8.3.8.a.2. Diarrhea;

8.3.8.a.3. Jaundice; or

8.3.8.a.4. Sore throat with fever; or

8.3.8.b. Have a lesion containing pus, such as a boil or infected wound, that is open or draining and is:

8.3.8.b.1. On the hands or wrists, unless an impermeable cover, such as single-use gloves, protects the lesion;

8.3.8.b.2. On exposed portions of the arms, unless the lesion is protected by an impermeable cover; or

8.3.8.b.3. On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage; or

8.3.8.c. Have symptoms of any of the following illnesses as diagnosed by a health practitioner:

8.3.8.c.1. Norovirus;

8.3.8.c.2. Hepatitis A;

8.3.8.c.3. Shigella spp;

8.3.8.c.4. Shiga toxin producing E. coli; or

8.3.8.c.5. Salmonella.

§61-42-9. Role of local health departments in cottage foods.

9.1. If the local health department in the jurisdiction in which a potentially hazardous cottage food vendor permittee is located has reason to believe that an imminent health hazard exists, the local health department may invoke a cessation of production until the hazardous situation has been addressed to the satisfaction of the local health department. A local health department that invokes cessation of production shall do so in consultation with WVDA.

§61-42-10. Enforcement.

10.1. If WVDA determines that any person is engaged in the home-based sale of a potentially hazardous cottage food without a potentially hazardous cottage food vendor permit, a notice shall be issued stating the person has thirty (30) days to apply for a vendor permit from the WVDA. Failure to apply for a vendor permit within thirty (30) days shall result in a \$250 civil penalty being assessed. If the penalty is not paid within thirty (30) days of the assessment, the account may be referred to collections.

10.2. If, in the course of any inspection carried out pursuant to the provisions of this rule, a violation of W. Va. Code §19-40-1 et seq. or of this rule is found to have been committed by a potentially hazardous cottage food vendor permit holder, or a vendor's food product is found to be adulterated or misbranded, the Commissioner shall send a written "First Notice" to the vendor permit holder. The First Notice shall identify the violation(s) at issue, explain the enforcement policy established by this section, and require that the permit holder remedy the violation(s) within seven days of receipt of the First Notice. A second inspection shall occur following the seven-day remedy period.

10.3. If the same violation(s) are found in the course of the second inspection, the Commissioner shall send a written "Second Notice" to the vendor permit holder. The Second Notice shall identify the violation(s) at issue and require the permit holder to develop a written plan to correct the violation(s), to implement the plan within seven days of receipt of the Second Notice, and to provide WVDA with a copy of the plan for review. A third inspection shall occur following WVDA's receipt and acceptance of the written correction plan.

10.4. If the same violation(s) are found in the course of the third inspection, the Commissioner shall issue an immediate "Suspension of Permit." The suspension order shall specify the reasons for the suspension and the length of time that the suspension will remain in effect.

10.4.1. A suspension order shall remain in effect until the vendor permit holder submits, and the Commissioner accepts, a written plan of correction for each identified violation and a request for reinstatement of the permit.

10.4.2. The Commissioner shall, within 10 business days of his or her receipt of the vendor permit holder's written plan of correction and request for reinstatement, either accept or deny the same. The Commissioner may accept the request for reinstatement if he or she determines that the written plan of correction's implementation will result in the vendor permit holder being in compliance with all applicable provisions of W. Va. Code §19-40-1 *et seq.* and of this rule. If the Commissioner denies the written plan and request for reinstatement, he or she shall inform the vendor permit holder of the decision in writing, identify any deficiencies in the written plan, and specify the terms and conditions under which the permit will be reinstated.

10.5. If, following the reinstatement of a suspended vendor permit and the resumption of operations by the vendor, the Commissioner finds that effective corrective actions have not been taken, he or she may either issue another Suspension of Permit or otherwise revoke the permit. The Commissioner shall, in the case of a permit revocation, send a written notice to the vendor permit holder specifying the reasons for the revocation.

10.6. A denial, suspension, or revocation of a potentially hazardous cottage food vendor permit is final 30 days following receipt of the notice of denial, suspension, or revocation, unless the relevant vendor, within the same 30-day period, gives the Commissioner written notice of a request for a hearing at which the order of denial, suspension, or revocation may be contested as contrary to law, unwarranted by the facts, or both. The provisions of W. Va. Code §29A-5-1 *et seq.* governing contested cases shall apply to all hearings conducted pursuant to this subsection. A vendor may also request an informal meeting with the Commissioner, or his or her designee, before requesting a hearing.

10.7. A person who performs a recall by voluntarily removing a product from sale or distribution in an effective manner, so as to limit the potential harm to the health and well-being of the public, may be eligible for certain exemptions from the enforcement policy set forth in this section. The Commissioner shall consider the facts of each case in determining whether to grant an exemption.

10.8. The Commissioner may suspend all or certain provisions of the enforcement policy set forth in this section in cases where such action is necessary to protect the public health, safety, and welfare.