

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amendment)

902 KAR 45:090. Home-based processors and farmers market home-based microprocessors.

RELATES TO: KRS 217.005-217.215, 217.290, 217.992, 217B.555, 217B.990~~[217B.500—217B.900]~~, 21 C.F.R. 113.83, 114.10, 114.83, 21 U.S.C 343(w)

STATUTORY AUTHORITY: KRS 194A.050, 217.125(1), 217.137, 217.138

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125, 217.137, and 217.138 authorize the Secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of home-based processors and home-based microprocessors. This administrative regulation establishes a uniform code for the manufacture and marketing of limited-based Kentucky grown home microprocessed food products at farmers markets, certified roadside stands, or from the microprocessor's farm and for the manufacture and marketing of limited home-based processor food products from the home, at a market, roadside stand, community event, or online.

Section 1. Definitions. (1) "Cabinet" is defined by KRS 217.015(3).

(2) "Certified roadside stand" means a physical location listed with the Kentucky Farm Bureau for the direct-to-consumer marketing of limited Kentucky grown and produced food products.

(3) "Easily cleanable" means that surfaces are readily accessible and made of a material and finish and so fabricated that residue can be effectively removed by normal cleaning methods.

(4) "Equipment" means articles used in the preparation and processing of food.

(5) "Farmer" is defined by KRS 217.015(59).

(6) "Farmers market" or "farmers market temporary food service establishment" is defined by KRS 217.015(60).

(7) "Food contact surfaces" means those surfaces with which food can come in contact, and those surfaces that drain onto surfaces that can come in contact with food.

(8) "Permitted kitchen" means a food service establishment or food processing firm that holds a valid permit to process food, pursuant to the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 to 217.215, and issued by the Cabinet for Health and Family Services.

(9) "Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of *Clostridium botulinum*, or in raw shell eggs, the growth of *Salmonella Enteritidis*. "Potentially hazardous food" includes:

(a) An animal food (a food of animal origin) that is raw or heat-treated;

(b) A food of plant origin that is heat-treated or consists of raw seed sprouts;

(c) Cut melons; and

(d) Garlic-in-oil mixtures that are not modified in a way that makes the product nonpotentially hazardous.

(10) "Primary ingredients" means an agricultural or horticultural product that:

(a) Has been grown, harvested, and processed by the farmer as a predominant ingredient of a food product with the exception of "flour", as defined by KRS 217.015(17), for use in:

1. "Bread" as defined by KRS 217.015(2); or
 2. Other items listed in KRS 217.015(56); and
- (b) Does not include oil, vinegar, sugar, and other seasonings or spices used in the production of home processed or microprocessed foods.
- (11) "Processing authority" means:
- (a) The Food Science Professionals of the University of Kentucky, Department of Agriculture, who review and approve established scheduled processes, for adequate process times and pressures for the size of jar, style of pack, and kind of food being canned, by home-based microprocessors; or
 - (b) A qualified entity in accordance with 21 C.F.R. 113.83 and 114.83.
- (12) "Single-service article" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one (1) time or one (1) person use after which they are intended for discard.
- (13) "Single-use article" means utensils and bulk food containers designed and constructed to be used once and discarded such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number ten (10) cans that do not meet the materials, durability, strength, and cleanability specifications for multiuse utensils.
- (14) "Utensil" means any food-contact implement used in the storage, preparation, transportation, dispensing, or sale of food.
- (15) "Ware-washing" means the cleaning and sanitizing of food-contact surfaces of equipment and utensils such as kitchenware.

Section 2. Limitations on Certain Home-based Processed and Home-based Microprocessed Food Products. (1) A home-based [fæəd] processor may[shall] produce:

- (a) [only these] Foods [as] listed in KRS 217.015(56);
- (b) Dried or freeze dried whole fruits or vegetables;
- (c) Candy that shall be:
 1. Produced without added alcohol; and
 2. Made with no bare-hand contact;
- (d) Maple syrup;
- (e) Pecan pies;
- (f) Granola that may be made with dried grains;
- (g) Trail or snack mix that may be made with dried fruit, nuts, or seeds; and
- (h) Popcorn that may be plain or have added seasonings.

(2) A home-based microprocessor shall produce [~~only these~~] foods as authorized by KRS 217.015(57).

(3) The following foods shall not be processed or offered for sale by a home-based processor or home-based microprocessor:

- (a) Crème filled pies;
- (b) Custard;
- (c) Custard pies;
- (d) Pies with meringue topping;
- (e) Cheesecake;
- (f) Cream, custard, or meringue pastries;
- (g) Raw seed sprouts;
- (h) Garlic-in-oil products; and
- (i) Pureed baby foods.

(4) Vacuum packaging of food in a container other than a mason-type jar shall be prohibit-

ed.

(5) A jam or jelly processed in less than ten (10) minutes shall be filled into a sterile empty jar. Sterilization shall be accomplished by submerging the jar in boiling water for:

- (a) At least ten (10) minutes at an altitude of less than 1,000 feet above sea level; and
- (b) One (1) additional minute for each additional 1,000 feet elevation above sea level.

(6) If a boiling-water canner is utilized in the production of food by a home-based processor, the canner shall be deep enough so that at least one (1) inch of briskly boiling water will be over the tops of jars during processing.

(7) If an electric range is used for heating, the boiling-water canner shall have a flat bottom and shall be no more than four (4) inches wider than the element on which it is heated.

Section 3. Standards for Home-based Processing. (1) A home-based processor shall maintain basic hygiene, cleanliness, and sanitation while producing home-based processor products and shall comply with the standards established in paragraphs (a) through (f) of this subsection during production, packaging, and handling of products for sale. The home-based processor shall:

- (a) Regularly wash hands with soap and water;
- (b) Keep kitchen equipment and utensils used for home-based processing clean and maintained in a good state of repair;
- (c) Wash, rinse, and sanitize all food contact surfaces, equipment, and utensils used for food preparation before each use;
- (d) Keep children under age twelve (12) and pets or other animals out of the kitchen during home-based processing related activities;
- (e) Cease performing any domestic activities in the kitchen, such as family meal preparation, dishwashing, or washing and drying laundry; and
- (f) Not produce, package, or handle any home-processed products while infected with a contagious disease or illness.

(2) A home-based processor doing business in the state shall be a resident of Kentucky.

(3) A home-based processor may advertise and accept orders and payments in person, electronically, or via the internet or phone.

(4) A home-based processor shall provide all home-based processed foods direct to the consumer through pick-up or delivery, and at flea markets, farmers markets, festivals, county fairs, craft fairs, and non-profit charity events, or a roadside stand.

(5) Home-based processed food products shall:

- (a) Be labeled as required by KRS 217.136(3); and
- (b) Contain allergen information as specified by 21 U.S.C. 343(w).

(6) A home-based processor shall not be required to have grown a primary ingredient for each of their products produced.

(7) Beginning January 1, 2020, a home-based processor shall register with the Department for Public Health, Food Safety Branch. A home-based processor shall submit:

- (a) A DFS-250 Application for Home-based Processor, available from the Kentucky Food Safety Branch or at University of Kentucky Extension Service Office; and
- (b) A fifty (50) dollar registration fee.

(8) The home-based processor registration shall be valid for one (1) year. A home-based processor registration shall expire March 31 of each year and is renewable upon submission of a DFS-250 and accompanied by an annual fee of fifty (50) dollars.

(9) Inspection of a home-based processor facility shall be made upon complaint, utilizing the [Form] DFS-252, Home-based Processor/Microprocessor Inspection Report.

Section 4. Home-based Microprocessor Certification. (1) A Kentucky farmer desiring to grow, harvest, process, and market Kentucky grown microprocessed food products and participate in the training program shall submit a DFS-251, Application for Home-based Microprocessor, which is available from the Department for Public Health, [Kentucky] Food Safety Branch or at University of Kentucky Extension Service Office.

(2) The application for certification shall be submitted to the cabinet and include the following information and attachments:

(a) Name and address, including:

1. The physical address and acreage of the farmland on which the primary food product ingredients are to be grown; and

2. The name and address of the property owner if not owned by the farmer;

(b) The name and address of the primary residence occupied by the farmer;

(c) Type of water source. Sufficient potable water for the needs of the facility shall be provided from a source constructed, maintained, and operated pursuant to applicable requirements established in 401 KAR Chapter 8;

(d) Type of sewage disposal. Sewage, including liquid waste, shall be disposed of by a public sewage system, or if a public sewer system is not available, sewage disposal shall be made into a private sewage disposal system designed, constructed, and operated in accordance with the requirements of 902 KAR Chapter 10 and 401 KAR Chapter 5;

(e) A listing of the food products to be processed and marketed by the farmer;

(f) Verification of attendance and successful completion of the Food Processing School including:

1. Verification of attendance and successful completion of the Food Processing School provided by the University of Kentucky Extension Office in compliance with KRS 217.015(58)(a) by the farmer for the manufacture of the microprocessed food products; or

2. Verification of attendance and successful completion of a food processing school approved pursuant to 21 C.F.R. 114.10; and

(g) Documentation from the processing authority for an established scheduled process for each food item that is to be processed by the home-based microprocessor.

1. Any change in the recipe shall constitute a recipe deviation, and a new review and approval shall be required from the processing authority prior to processing.

2. Each additional product shall have a separate written established scheduled process and shall be submitted to the processing authority for review prior to processing.

3. All established scheduled processes shall be maintained and made available upon request by the cabinet.

(3)(a) Prior to marketing home-based products, the application for home-based microprocessor, along with the required water source approval, shall be submitted to the cabinet.

(b) The cabinet shall notify the applicant if the application is approved or denied.

(c) If the application is approved, the home-based microprocessor may begin marketing home-based products.

(d) If the application is denied:

1. The cabinet shall notify the applicant in writing of the reasons for the denial; and

2. The home-based microprocessor may appeal in accordance with Section 9(5) of this administrative regulation.

(4) Product labels for home-based microprocessed foods shall be labeled in accordance with KRS 217.005 to 217.215 and 21 U.S.C. 343(w). Draft copies of all home-based microprocessed food product labels shall be submitted for review by the cabinet prior to labeling and marketing.

(5) The certification requirements established in this subsection shall apply to a home-based

microprocessor.

(a) Each home-based microprocessor certification shall be issued only for the premises and person named in the application and shall be nontransferable.

(b) The certification shall be posted in a conspicuous place in the processing establishment and a copy shall be posted at the point of sale.

(c) Home-based microprocessed food products shall only be marketed by the certificate holder that processed the food product.

(6) Each home-based microprocessor certification shall be valid for one (1) year, unless previously suspended or revoked. A home-based microprocessor certification shall expire March 31 of each year and shall be renewable annually upon submittal of an application accompanied by an annual fee of fifty (50) dollars.

(7) Attendance at a food processing school as required by subsection (2)(f) of this section shall be required every three (3) years or upon any change or addition of food products to be processed.

Section 5. Production Standards for Home-based Microprocessors. (1) At all times, including while being stored, prepared, offered, dispensed, or transported, food ingredients and processed products shall be protected from:

(a) Cross-contamination; and

(b) Potential contamination by:

1. Insects;
2. Insecticides;
3. Rodents;
4. Rodenticides;
5. Unclean equipment or utensils;
6. Unnecessary hand contact;
7. Draining;
8. Overhead leakage or condensation;
9. Dust;
10. Coughs;
11. Sneezes; or
12. Other agents of public health significance.

(2) Pets and other animals shall not be allowed in the kitchen and shall be kept out of food preparation areas during microprocessing related activities.

(3) Children under age twelve (12) shall not be allowed in the kitchen area during microprocessing related activities.

(4) Smoking or use of any form of tobacco shall not be allowed in the kitchen area during microprocessing related activities.

(5) Laundry facilities may be present in the residential kitchen, but shall not be used during microprocessing related activities.

(6) Home-based microprocessors shall restrict the use of the food preparation area during any processing activity. Cooking facilities, in the residential kitchen, shall not be available for personal use during home-based microprocessing activities.

(7) Vehicles used in transporting home-based microprocessed food products shall be maintained in a safe and sanitary manner in accordance with KRS 217.290. Vehicle compartments used to transport animals shall not be used for transporting home-based microprocessed foods.

(8) Products made by a home-based microprocessor shall not be used or offered for consumption in a retail food establishment or through interstate commerce.

(9) Food Supplies.

(a) The primary ingredients used in home-based microprocessed products shall have been grown by the microprocessor.

(b) All other ingredients in the products shall be in sound condition, safe for human consumption, obtained from a state or federal permitted food manufacturer, and stored and protected separate and apart from personal use food ingredients.

(c) Prior to processing, the temperature of potentially hazardous foods shall be forty-one (41) degrees Fahrenheit or below, or 135 degrees Fahrenheit or above, except during necessary times of preparation.

~~(d) [Only food-grade lime shall be used for soaking foods prior to pickling.~~

~~(e)~~ Jar seals for microprocessed foods shall be inspected within twelve (12) to twenty-four (24) hours after cooling. A container inspected and found to not be properly sealed shall be discarded. Reprocessing of an unsealed jar shall be prohibited.

~~(e)~~~~(f)~~ For each microprocessed food item, the headspace above the food in a jar and below its lid shall be in compliance with the established scheduled process for that food.

~~(f)~~~~(g)~~ Hermetically-sealed packages shall be handled so as to maintain product and container integrity.

~~(g)~~~~(h)~~ A product processed by a home-based microprocessor shall be packaged in food grade material.

(10)(a) Food shall be prepared:

1. With a minimum of bare hand contact;
2. On a food-contact surface; and
3. With clean utensils that have been sanitized.

(b) Raw fruits and raw vegetables that will be cooked, cut, or combined with other ingredients or that will be otherwise processed into food products by the home-based microprocessor shall first be thoroughly cleaned with potable water.

(11) Equipment and utensils. (a) Equipment.

1. Equipment shall be deemed adequate by the processing authority for the food being processed. Use of boiling water canners shall be prohibited for processing of low-acid canned foods.

2. Open-kettle canning and the processing of freshly-filled jars in a conventional oven, microwave oven, or dishwasher shall be prohibited.

3. All low-acid food shall be sterilized at temperatures of 240 to 250 degrees Fahrenheit, in pressure canners operated at ten (10) to fifteen (15) PSIG as measured by a dial gauge, or weighted gauge if deemed appropriate by the processing authority. The processing authority shall ensure that each weighted-gauge pressure canner utilized by a microprocessor is operated at the correct pressure for the corresponding altitude.

4. A pressure canner shall not have been manufactured prior to year 2000, and the manufacturer shall currently be in business with the ability to provide canner parts and calibration of temperature dial gauges.

5. A pressure canner utilized in the microprocessing of foods shall, at minimum;

a.~~[;]~~ Be of a sixteen (16) quart capacity; and

b. ~~[, which shall]~~ Contain at least~~[no more than]~~ seven (7) quart jars during processing.

6. Use of pressure saucepans with less than sixteen (16) quart capacities shall be prohibited.

7.~~[6;]~~ Each temperature dial gauge shall be annually verified for accuracy by the manufacturer of the canner or other qualified laboratory. Verification records shall be maintained by the home-based microprocessor and shall be made available to the cabinet upon request.

8.~~[7;]~~ A timing device shall be available and used to verify appropriate processing time as

designated in the established scheduled process.

9.[8-] Only regular and wide-mouth mason-type, threaded, home-canning jars with self-sealing, two (2) piece canning lids with screw bands shall be used for microprocessed foods. Mayonnaise-type jars, jars with wire bails and glass caps, and one (1) piece zinc porcelain-lined caps shall be prohibited.

(b) Equipment and utensils shall be:

1. Constructed and repaired with safe materials, including finishing materials;
2. Corrosion resistant and nonabsorbent;
3. Maintained in good repair; and
4. Smooth, easily cleanable, and durable under conditions of normal use.

(c) Single-service articles shall be made from clean, sanitary, and safe materials.

(d) Equipment, utensils, and single-service articles shall not impart odors, color, taste, or contaminants to food.

(e) Single-service and single-use articles shall not be reused.

(f) Safe plastic or rubber-like materials that are resistant, under normal conditions of use, to scratching, scoring, decomposition, crazing, chipping, or distortion, and are of sufficient weight and thickness to permit cleaning and sanitizing by normal ware-washing methods shall be permitted for repeated use.

Section 6. Sanitation Requirements for Home-based Microprocessors. (1) A farmer or processing assistant shall not process food in a home-based microprocessing facility while there is a likelihood of contaminating food or a food-contact surface, or transmitting a disease to another person, if the individual is:

(a) Infected with a communicable disease that can be passed by food;

(b) A carrier of an organism that causes a communicable disease;

(c) Affected with a boil, infected wound, or acute respiratory infection; or

(d) Has a symptom caused by illness, infection, or other source that is associated with an acute gastrointestinal illness such as diarrhea, fever, vomiting, jaundice, or sore throat with fever.

(2)(a) Each person engaged in a food preparation and ware-washing operation of a home-based microprocessing facility shall wash his or her hands and exposed portions of arms thoroughly, with soap or detergent and warm water:

1. Before starting work;
2. After smoking;
3. After eating;
4. After handling nonwashed fruits and vegetables;
5. After using the toilet; and
6. As often as is necessary during work to keep hands and forearms clean.

(b) A hand-washing facility with hot and cold potable water shall comply with the requirements of 815 KAR 7:125, and shall be conveniently located.

(c) A supply of hand-cleaning soap or detergent shall be available at each hand-washing facility.

(d) A supply of sanitary towels or a hand-drying device providing heated air shall be conveniently located near each hand-washing facility.

(e) An easily-cleanable waste receptacle shall be conveniently located near the hand-washing facility.

(f) A soap dispenser and disposable towels for use in hand-washing shall be provided at the kitchen sink. This sink shall not be used for hand-washing after toilet use.

(g) Hand-washing facilities, soap, detergent dispensers, hand-drying devices, and all related

facilities shall be kept clean and in good repair.

(3) Each worker of a home-based microprocessing facility shall keep his or her fingernails trimmed and clean.

(4) Each worker of a home-based microprocessing facility shall wear clean outer clothing.

(5) Each worker in the food preparation area of a home-based microprocessing facility shall wear a hairnet, hat, scarf, or similar hair covering that effectively restrains head and facial hair.

(6) Each worker of a home-based microprocessing facility shall maintain a high degree of personal cleanliness and shall conform to good hygienic practices during working periods.

(7) Each worker of a home-based microprocessing facility shall consume food or use tobacco only in designated areas. A designated area shall not be located in a food preparation area or in an area where the worker's activity could result in contamination of food, water, equipment, or utensils.

(8) Cleaning and sanitizing of equipment and utensils.

(a) Food utensils and equipment shall be stored in a manner to avoid contamination.

(b) Food-contact surfaces and sinks shall be smooth and easily cleanable.

(c) Food-contact equipment, surfaces, and utensils shall be cleaned and sanitized prior to microprocessing related activities and after each use.

(d) Sinks, basins, or other receptacles used for cleaning of equipment and utensils shall be cleaned and sanitized before use.

(e) Equipment and utensils shall be prerinsed or prescraped and, if necessary, presoaked to remove food particles and soil.

(f) Manual cleaning and sanitizing shall be conducted as established in subparagraphs 1. through 5. of this paragraph.

1. For manual cleaning and sanitizing of cooking equipment, and utensils, three (3) compartments shall be provided and used. A two (2) compartment sink, with an additional portable tub may be used.

2. Each of the following five (5) steps of the ware-washing process shall be completed:

a. Prerinsing or scraping;

b. Washing with hot detergent solution;

c. Rinsing to remove abrasives and cleaning chemicals;

d. Sanitizing, using a method approved by the applicable provisions of 902 KAR 45:005, Section 2, the Kentucky Food Code; and

e. Air-drying and draining.

3. Washing, rinsing, and sanitizing solutions shall be maintained in a clean condition.

4. The washing solution shall be maintained at a minimum temperature of at least ninety-five (95) degrees Fahrenheit.

5. Chemical sanitizer shall not have a concentration higher than the maximum permitted by law. A test kit or other device shall be provided to measure the parts per million concentration of the solution.

(g) Mechanical cleaning and sanitizing shall be conducted as established in this subsection. A domestic or home-style dishwasher may be used if the performance criteria established in this subsection are met.

1. The dishwasher shall effectively remove physical solids from all surfaces of dishes.

2. The dishwasher shall sanitize dishes by the application of sufficient accumulative heat.

3. The operator shall provide and use daily a maximum registering thermometer or a heat thermal label to determine that the dishwasher's internal temperature is at least 150 degrees Fahrenheit after the final rinse and drying cycle.

4. The dishwasher shall be installed and operated according to manufacturer's instructions for the highest level possible while sanitizing the kitchen facility's utensils and tableware. A

copy of the manufacturer's instructions shall be available on the premises.

(h) There shall be sufficient area or facilities, such as portable dish tubs and drain boards, for the proper handling of:

1. Soiled utensils prior to washing; and
2. Cleaned utensils after sanitizing.

(i) Manually-cleaned equipment, utensils, and tableware shall be air-dried.

(9) Toilet facilities.

(a) Toilet facilities shall be:

1. Installed pursuant to requirements of 815 KAR 7:125;
2. Conveniently located; and
3. Accessible to workers at all times.

(b) A toilet facility, including toilet fixtures and a related vestibule, shall be kept clean and in good repair. A supply of toilet tissue shall be provided at each toilet at all times. Easily cleanable receptacles shall be provided for waste materials.

(10) The floors, walls, ceilings, and attached equipment in food preparation and storage areas and in workers bathrooms of a home-based microprocessor facility shall be fabricated from easily cleanable material, maintained in good repair, and kept clean.

(11) Artificial lighting shall be provided sufficient to facilitate sanitary food handling and cleaning of facilities.

(12) The use and storage of pesticides and rodenticides.

(a) A person shall not apply insecticides or rodenticides except:

1. In accordance with requirements of KRS 217B.500 to 217B.990 and 302 KAR Chapter 29;
2. In accordance with the manufacturer's labeling; and
3. In such a way that food, food-contact surfaces, and the supply of potable water shall not be contaminated.

(b) Open pesticide or rodenticide bait boxes shall not be used.

(c) Pesticides, rodenticides, and other toxic materials shall be stored apart from food, equipment, and utensils. Every container of toxic material shall be clearly labeled for easy identification.

(d) Pesticides and rodenticides shall be stored separated from other toxic and chemical compounds at all times.

(13) Garbage and refuse shall be disposed of often enough and in a manner to prevent the development of objectionable odors and the attraction of pests. If garbage or refuse is burned on the premises, it shall be done by controlled incineration that prevents the escape of particulate matter pursuant to 401 KAR Chapter 63.

Section 7. Microprocessors Utilizing Permitted Kitchens. (1) A microprocessor may elect to process food products utilizing a kitchen that currently holds a valid permit to operate issued by the cabinet.

(2) A microprocessor utilizing a permitted kitchen shall comply with Sections 2, 4, 5, and 6 of this administrative regulation.

(a) A microprocessor utilizing a permitted kitchen shall provide a copy of a signed, written agreement between the facility owner and the farmer that authorizes the use of the permitted kitchen for microprocessing and the name, address, and permit number of the facility.

(b) Microprocessed food products shall not be made during periods of time while the permitted facility is in operation.

(c) Microprocessed food products shall be stored at the farmer's primary residence and shall be maintained separate and apart from the personal use food supplies.

(d) Microprocessed food products made in a permitted kitchen shall only be sold at farmers markets, certified roadside stands, or from the microprocessor's farm.

Section 8. Inspections, Notices, Records. (1) Inspections. At least once every four (4) years, the cabinet shall inspect each home-based microprocessor and shall make as many additional inspections and reinspections as are necessary for the enforcement of this administrative regulation.

(2) Inspection records. The cabinet representative inspecting a home-based microprocessor shall record the findings on the [Form] DFS 252, Home-based Processor/Microprocessor Inspection Report, and shall provide a copy of the inspection report to the certificate holder or his representative in charge.

(3) Issuances of notices. If an inspection reveals a violation of this administrative regulation, the cabinet shall notify the certificate holder or the certificate holder's representative in charge. In the notification, the cabinet shall establish:

(a) The specific violations found; and

(b) A specific and reasonable period of time for the correction of the violations found pursuant to this paragraph. The report of inspection shall state:

1. Failure to comply with a notice from the cabinet or local health department, or with a time limit for correction of a violation, shall result in regulatory action up to and including suspension of the certificate, as provided in KRS 217.126;

2. An opportunity for appeal from an adverse notice or inspection finding shall be provided if a written request is filed with the cabinet within ten (10) days following service of notice, in accordance with 902 KAR 1:400; and

3. Failure to comply with a notice issued in accordance with the provisions of this administrative regulation may result in suspension of the certificate.

(4) Service of notice. A notice provided for under this section shall be properly served if a copy of the DFS-252 inspection report form or other notice has been delivered personally to the certificate holder or person in charge, or the notice has been sent by registered or certified mail, return receipt requested, to the last known address of the certificate holder. A copy of the notice shall be filed with the cabinet.

(5) The cabinet shall maintain a record of all certified home-based microprocessors and shall provide this information to the University of Kentucky Cooperative Extension Service Office and local health departments.

Section 9. Certificate Suspension, Revocation, or Denial. (1) A home-based microprocessor certificate shall be suspended immediately, upon notice to the certificate holder, if:

(a) The cabinet has reason to believe that an imminent public health hazard exists; or

(b) The certificate holder has interfered with the cabinet in the performance of its duties.

(2) Except as provided in subsection (1) of this section, the cabinet shall allow a certificate holder a reasonable opportunity to correct a violation. The cabinet shall notify, in writing, a certificate holder or operator who fails to comply with a written notice issued under the provisions of this administrative regulation that the certificate shall be suspended at the end of ten (10) days following service of the notice, unless a written request is filed in accordance with 902 KAR 1:400.

(3) Reinstatement of suspended certificate. A person whose certificate has been suspended may make application for a reinspection in accordance with 902 KAR 1:400.

(4) Revocation of certificate. For serious or repeated violations of the requirements of this administrative regulation, or for interference with the cabinet in the performance of its duties, a certificate may be permanently revoked. Before a permanent revocation action is taken, the

cabinet shall notify the certificate holder in writing, stating the reasons the certificate is subject to revocation and advising that the certificate shall be permanently revoked at the end of ten (10) days following service of the notice, unless a request for an appeal is filed in accordance with 902 KAR 1:400. A certificate may be suspended for cause pending revocation.

(5) Denial. Any applicant denied the issuance of a certificate by the cabinet within ten (10) days of service of the notice may appeal the certificate denial in accordance with 902 KAR 1:400.

Section 10. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "DFS-250, Application for Home-based Processor", 03/19;

(b) "DFS-251, Application for Home-based Microprocessor", 05/18; and

(c) ~~(b)~~ "DFS-252, Home-based Processor/Microprocessor Inspection Report", 05/18.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Cabinet for Health and Family Services, 275 East Main Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

JEFFREY D. HOWARD, JR., M.D., Commissioner

ADAM M. MEIER, Secretary

APPROVED BY AGENCY: June 12, 2019

FILED WITH LRC: June 14, 2019 at 10 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on July 22, 2019, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by July 15, 2019, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until July 31, 2019. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Chase Coffey, Executive Administrative Assistant, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Persons: Julie Brooks or Chase Coffey

(1) Provide a brief summary of:

(a) What this administrative regulation does: This emergency administrative regulation establishes the requirements for all home-based processed foods, and distinguishes between a home-based processor and a home-based microprocessor.

(b) The necessity of this administrative regulation: House bill 468, enacted during the 2019 legislative session, modified the definitions of a home-based processor and home-based microprocessor listed in KRS 217.015; and modified KRS 217.136 and KRS 217.137 to authorize the cabinet to further delineate which food products could be produced by a home-based pro-

cessor and home-based microprocessor through the promulgation of administrative regulations. KRS 217.136 was modified to require a home-based processor to register with the department effective January 1, 2020.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This emergency administrative regulation delineates which foods may be produced by a home-based processor and home-based microprocessor, and adds the registration process for a home-based processor.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This emergency administrative regulation will allow home-based processor and home-based microprocessors who are currently producing foods such as dried herbs and spices, nuts and grains to continue to do so.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment further delineates the types of foods that can be produced by a home-based processor and a home-based microprocessor; and adds a registration process for a home-based processor.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to address the changes in KRS 217.015, KRS 217.136, and KRS 217.137 as a result of the passage of House Bill 468.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 217.015 adds additional food items that can be produced by a home-based processor and a home-based microprocessor. KRS 217.136 authorizes the cabinet to promulgate administrative regulations to further delineate which food products can be produced by a home-based processor and adds a registration process for a home-based processor. KRS 217.137 authorizes the cabinet to promulgate administrative regulations to further delineate which food products can be produced by a home-based microprocessor.

(d) How the amendment will assist in the effective administration of the statutes: This emergency amendment will help to ensure home-based processors and home-based microprocessors who are established to offer dried herbs and spices, nuts, and grains are able to do so during the current farmers' market season. This amendment also requires a home-based processor to register with the Food Safety Branch. While a routine inspection is not required, the registration process will assist in a complaint investigation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There are 140 microprocessors currently operating under this administrative regulation. Because the registration of home-based processors was previously removed from this administrative regulation the Food Safety Branch does not know exactly how many home-based processors will be affected by this administrative regulation. Previously there were 776 home-based processors registered with the branch.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: Home-based processors and home-based microprocessors will need to be aware of the expanded food products available for home processing. Home-based processors will need to be aware of the registration process that becomes effective January 1, 2020.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): Beginning January 1, 2020, home-based processors will pay a \$50 registration fee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Home-based processors and home-based microprocessors will be able to offer an expanded variety of home produced food products.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: The current cost to administer all programs under the Food Safety Branch within the Division of Public Health Protection and Safety is \$5,524,622. There is no anticipated increase in cost as a result of this amendment.

(b) On a continuing basis: There is no anticipated increase in cost as a result of this amendment.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Agency funds and revenue generated by the registration process for home-based processors and microprocessors.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: There are no anticipated increase in costs to administer this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. Home-based processors and home-based microprocessors will be assessed a fifty (50) dollar registration fee.

(9) TIERING: Is tiering applied? Yes, tiering has been applied as there are separate requirements for home-based processors and microprocessors. All home-based processors will be required to comply with KRS 217.136 and the applicable provisions of this administrative regulation. Home-based microprocessors will be required to comply with KRS 217.137 and the provisions of this administrative regulation.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This program is administered by the Food Safety Branch within the Department for Public Health, with inspection of the home-based microprocessors conducted by state Food Manufacturing Section Inspectors. Local health departments may refer any complaints received to the Food Safety Branch. The only other entity that may be impacted will be the Division of Water to approve the water source for microprocessors without a municipal water supply.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 217.136, 217.137.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The 776 previously registered home-based processors should generate an estimated \$38,800 in the first year of registration beginning January 1, 2020. The 140 home-based microprocessors will generate an estimated \$7,000 in certification fees. (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The combined registration fees for home-based processors and home-based microprocessors will generate an estimated \$45,800 in subsequent years.

(c) How much will it cost to administer this program for the first year? The current cost to

administer all programs under the Food Safety Branch within the Division of Public Health Protection and Safety is \$5,524,622. There is no anticipated increase in costs to administer the home-based processor and home-based microprocessor registration program this first year.

(d) How much will it cost to administer this program for subsequent years? There is no anticipated increase in costs to administer the home-based processor and home-based microprocessor registration program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 21 C.F.R. 113.83, 114.10, 114.83 and 21 U.S.C. 343(w)

2. State compliance standards. KRS 217.138 establishes the home-based microprocessor certification program. KRS 217.135 authorizes the secretary to establish a standard of identity of any food or class of food promulgated under authority of the federal act.

3. Minimum or uniform standards contained in the federal mandate. Individuals seeking certification as a microprocessor are required to complete the training program pursuant to 21 C.F.R. 113.83, 114.10 and 114.83 offered by the University of Kentucky Cooperative Extension Service as the processing authority. The Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 343(w)) requires foods be labeled with the common or usual name of a major food allergen.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose stricter requirements.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. This administrative regulation does not impose stricter requirements.