

**CHAPTER 42****(HB 391)**

AN ACT relating to the marketing of home-processed foods.

*Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

Section 1. KRS 217.015 is amended to read as follows:

For the purposes of KRS 217.005 to 217.215:

- (1) "Advertisement" means all representations, disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics;
- (2) "Bread" and "enriched bread" mean only the foods commonly known and described as white bread, white rolls, white buns, enriched white bread, enriched rolls, and enriched white buns, as defined under the federal act. ***For the purposes of Sections 2 and 3 of this Act, "bread" or "enriched bread" also means breads that may include vegetables or fruit as an ingredient;***
- (3) "Cabinet" means the Cabinet for Health Services or its designee;
- (4) "Color" means but is not limited to black, white, and intermediate grays;
- (5) "Color additive" means a material that:
  - (a) Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source. Nothing in this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest; or
  - (b) When added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable, alone or through reaction with another substance, of imparting color. "Color additive" does not include any material that has been or may in the future be exempted under the federal act;
- (6) "Contaminated with filth" means any food, drug, device, or cosmetic that is not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminants;
- (7) "Cosmetic" means:
  - (a) Articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; and
  - (b) Articles intended for use as a component of those articles, except that the term shall not include soap;
- (8) "Device," except when used in subsection (48) of this section, KRS 217.035(6), KRS 217.065(3), KRS 217.095(3), and KRS 217.175(10), means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended:

- (a) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or
  - (b) To affect the structure or any function of the body of man or other animals;
- (9) "Dispense" means to deliver a drug or device to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for that delivery;
- (10) "Dispenser" means a person who lawfully dispenses a drug or device to or for the use of an ultimate user;
- (11) "Drug" means:
- (a) Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;
  - (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;
  - (c) Articles, other than food, intended to affect the structure or any function of the body of man or other animals; and
  - (d) Articles intended for use as a component of any article specified in this subsection but does not include devices or their components, parts, or accessories;
- (12) "Enriched," as applied to flour, means the addition to flour of vitamins and other nutritional ingredients necessary to make it conform to the definition and standard of enriched flour as defined under the federal act;
- (13) "Environmental Pesticide Control Act of 1972" means the Federal Environmental Pesticide Control Act of 1972, Pub. L. 92-516, and all amendments thereto;
- (14) "Fair Packaging and Labeling Act" means the Fair Packaging and Labeling Act as it relates to foods and cosmetics, 15 U.S.C. secs. 1451 et seq., and all amendments thereto;
- (15) "Federal act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. secs. 301 et seq., 52 Stat. 1040 et seq., or amendments thereto;
- (16) "Filled milk" means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, frozen, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, except the fat or oil of contained eggs and nuts and the fat or oil of substances used for flavoring purposes only, so that the resulting product is an imitation or semblance of milk, cream, skimmed milk, ice cream mix, ice cream, or frozen desserts, whether or not condensed, evaporated, concentrated, frozen, powdered, dried, or desiccated, whether in bulk or in containers, hermetically sealed or unsealed. This definition does not mean or include any milk or cream from which no part of the milk or butter fat has been extracted, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added any substance rich in vitamins, nor any distinctive proprietary food compound not readily mistaken for milk or cream or for condensed, evaporated, concentrated, powdered, dried, or desiccated milk or cream, if the compound is prepared and designed for the feeding of infants or young children, sick or infirm persons, and customarily used on the order of a physician, and is packed in individual containers bearing a label in bold type that the

contents are to be used for those purposes; nor shall this definition prevent the use, blending, or compounding of chocolate as a flavor with milk, cream, or skimmed milk, desiccated, whether in bulk or in containers, hermetically sealed or unsealed, to or with which has been added, blended or compounded no other fat or oil other than milk or butter fat;

- (17) "Flour" means only the foods commonly known as flour, white flour, wheat flour, plain flour, bromated flour, self-rising flour, self-rising white flour, self-rising wheat flour, phosphated flour, phosphated white flour, and phosphated wheat flour, defined under the federal act;
- (18) "Food" means:
- (a) Articles used for food or drink for man or other animals;
  - (b) Chewing gum; and
  - (c) Articles used for components of any such article;
- (19) "Food additive" means any substance the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any of these uses, if the substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food to be safe under the conditions of its intended use; except that the term does not include:
- (a) A pesticide chemical in or on a raw agricultural commodity;
  - (b) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity;
  - (c) A color additive; or
  - (d) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the federal act; the Poultry Products Inspection Act, 21 U.S.C. secs. 451 et seq.; or the Meat Inspection Act of 1907; and amendments thereto;
- (20) "Food processing establishment" means any commercial establishment in which food is manufactured, processed, or packaged for human consumption, but does not include retail food establishments, *home-based processors, or home-based microprocessors*;
- (21) "Food service establishment" means any fixed or mobile commercial establishment that engages in the preparation and serving of ready-to-eat foods in portions to the consumer, including but not limited to: restaurants; coffee shops; cafeterias; short order cafes; luncheonettes; grills; tea rooms; sandwich shops; soda fountains; taverns; bars; cocktail lounges; nightclubs; roadside stands; industrial feeding establishments; private, public or nonprofit organizations or institutions routinely serving food; catering kitchens; commissaries; charitable food kitchens; or similar places in which food is prepared for sale or service on the premises or elsewhere with or without charge. It does not include food vending machines, establishments serving beverages only in single service or original

containers, or retail food stores which only cut, slice, and prepare cold-cut sandwiches for individual consumption;

- (22) "Food storage warehouse" means any establishment in which food is stored for subsequent distribution;
- (23) "Immediate container" does not include package liners;
- (24) "Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent illness or injury based on:
  - (a) The number of potential illnesses or injuries; or
  - (b) The nature, severity, and duration of the anticipated illness or injury;
- (25) "Interference" means threatening or otherwise preventing the performance of lawful inspections or duties by agents of the cabinet during all reasonable times of operation;
- (26) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of KRS 217.005 to 217.215 that any word, statement, or other information appearing on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of the article, or is easily legible through the outside container or wrapper;
- (27) "Labeling" means all labels and other written, printed, or graphic matter:
  - (a) Upon an article or any of its containers or wrappers; or
  - (b) Accompanying the article;
- (28) "Legend drug" means a drug defined by the Federal Food, Drug and Cosmetic Act, as amended, and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription.";
- (29) "Meat Inspection Act" means the Federal Meat Inspection Act, 21 U.S.C. secs. 71 et seq., 34 Stat. 1260 et seq., including any amendments thereto;
- (30) "New drug" means:
  - (a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or
  - (b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety for use under prescribed conditions, has become so recognized, but which has not, otherwise than in the investigations, been used to a material extent or for a material time under the conditions;
- (31) "Official compendium" means the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them;
- (32) "Person" means an individual, firm, partnership, company, corporation, trustee, association, or any public or private entity;

- (33) "Pesticide chemical" means any substance that alone in chemical combination, or in formulation with one or more other substances, is an "economic poison" within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act and amendments thereto, and that is used in the production, storage, or transportation of raw agricultural commodities;
- (34) "Poultry Products Inspection Act" means the Federal Poultry and Poultry Products Inspection Act, 21 U.S.C. secs. 451 et seq., Pub. L. 85-172, 71 Stat. 441, and any amendments thereto;
- (35) "Practitioner" means medical or osteopathic physicians, dentists, chiropractors, and veterinarians who are licensed under the professional licensing laws of Kentucky to prescribe and administer drugs and devices. "Practitioner" includes optometrists when administering or prescribing pharmaceutical agents authorized in KRS 320.240(12) to (14), advanced registered nurse practitioners as authorized in KRS 314.011 and 314.042, and physician assistants when administering or prescribing pharmaceutical agents as authorized in KRS 311.858;
- (36) "Prescription" means a written or oral order for a drug or medicine, or combination or mixture of drugs or medicines, or proprietary preparation, that is signed, given, or authorized by a medical, dental, chiropractor, veterinarian, or optometric practitioner, and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
- (37) "Prescription blank" means a document that conforms with KRS 217.216 and is intended for prescribing a drug to an ultimate user;
- (38) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing;
- (39) "Retail food establishment" means any food service establishment, retail food store, or a combination of both within the same establishment;
- (40) "Retail food store" means any fixed or mobile establishment where food or food products, including prepackaged, labeled sandwiches or other foods to be heated in a microwave or infrared oven at the time of purchase, are offered for sale to the consumer, and intended for off-premises consumption, but does not include establishments which handle only prepackaged, snack-type, nonpotentially hazardous foods, markets that offer only fresh fruits and vegetables for sale, food service establishments, food and beverage vending machines, vending machine commissaries, or food processing establishments;
- (41) "Salvage distributor" means a person who engages in the business of distributing, peddling, or otherwise trafficking in any salvaged merchandise;
- (42) "Salvage processing plant" means an establishment operated by a person engaged in the business of reconditioning, labeling, relabeling, repackaging, reconditioning, sorting, cleaning, culling or who by other means salvages, sells, offers for sale, or distributes for human or animal consumption or use any salvaged food, beverage, including beer, wine and distilled spirits, vitamins, food supplements, dentifrices, cosmetics, single-service food containers or utensils, containers and packaging materials used for foods and cosmetics, soda straws, paper napkins, or any other product of a similar nature that has been damaged or contaminated by fire, water, smoke, chemicals, transit, or by any other means;
- (43) "Second or subsequent offense" has the same meaning as it does in KRS 218A.010;

- (44) "Secretary" means the secretary of the Cabinet for Health Services;
- (45) "Temporary food service establishment" means any food service establishment which operates at a fixed location for a period of time, not to exceed fourteen (14) consecutive days;
- (46) "Traffic" has the same meaning as it does in KRS 218A.010;
- (47) "Ultimate user" has the same meaning as it does in KRS 218A.010;
- (48) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts that are material in the light of the representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under the conditions of use as are customary or usual;
- (49) The representation of a drug in its labeling or advertisement as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involving prolonged contact with the body;~~and~~
- (50) The provisions of KRS 217.005 to 217.215 regarding the selling of food, drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of those articles for sale, the sale, dispensing, and giving of those articles, and the supplying or applying of those articles in the conduct of any food, drug, or cosmetic establishment;
- (51) ***"Home" means a primary residence occupied by the processor, that contains only two (2) ranges, ovens, or double-ovens, and no more than three (3) refrigerators used for cold storage. This equipment shall have been designed for home use and not for commercial use, and shall be operated in the kitchen within the residence;***
- (52) ***"Formulated acid food product" means an acid food in which the addition of a small amount of low-acid food results in a finished equilibrium pH of 4.6 or below that does not significantly differ from that of the predominant acid or acid food;***
- (53) ***"Acidified food product" means a low-acid food to which acid or acidic food is added and which has a water activity value greater than 0.85, and a finished equilibrium pH of 4.6 or below;***
- (54) ***"Low-acid food" means foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6, and a water activity value greater than 0.85;***
- (55) ***"Acid food" means foods that have a natural pH of 4.6 or below;***
- (56) ***"Home-based processor" means a farmer who, in the farmer's home, produces or processes whole fruit and vegetables, mixed-greens, jams, jellies, sweet sorghum syrup, preserves, fruit butter, bread, fruit pies, cakes, or cookies; and***
- (57) ***"Home-based microprocessor" means a farmer who, in the farmer's home or certified or permitted kitchen, produces or processes acid foods, formulated acid food products,***

*acidified food products, or low-acid canned foods, and who has a net income of less than thirty-five thousand dollars (\$35,000) annually from the sale of the product;*

- (58) *"Certified" means any person or home-based microprocessor who:*
- (a) *Has attended the Kentucky Cooperative Extension Service's microprocessing program or pilot microprocessing program and has been identified by the Kentucky Cooperative Extension Service as having satisfactorily completed the prescribed course of instruction; or*
  - (b) *Has attended some other school pursuant to 21 C.F.R. sec. 114.10; and*
- (59) *"Farmer" means a person who is a resident of Kentucky and owns or rents agricultural land pursuant to subsection (9) of KRS 132.010 or horticultural land pursuant to subsection (10) of KRS 132.010. For the purposes of Sections 2 to 5 of this Act, "farmer" also means any person who is a resident of Kentucky and has grown the primary horticultural and agronomic ingredients used in the home-based processed products which they have produced.*

SECTION 2. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED TO READ AS FOLLOWS:

- (1) *A home-based processor shall be exempt from KRS 217.035, 217.037, and 217.125 if the following conditions are met:*
- (a) *All finished product containers are clean, sanitary, and properly labeled pursuant to subsection (3) of this section;*
  - (b) *All home-processed foods produced under this exemption are neither adulterated nor misbranded pursuant to subsection (4) of this section; and*
  - (c) *All glass containers for jams, jellies, preserves, fruit butter, and similar products are provided with suitable rigid metal covers.*
- (2) *A home-based processor shall not produce or process for sale acid foods, acidified food products, formulated acid food products, or low-acid canned foods.*
- (3) *A home-based processor shall label each of its food products and include the following information on the label of each of its food products:*
- (a) *The name and address of the home-based processing operation;*
  - (b) *The common or usual name of the food product;*
  - (c) *The ingredients of the food product, in descending order of predominance by weight;*
  - (d) *The net weight and volume of the food product by standard measure, or numerical count;*
  - (e) *The following statement in ten (10) point type: "This product is home-produced and processed"; and*
  - (f) *The date the product was processed.*
- (4) *Food products identified in subsection (56) of Section 1 of this Act and not labeled in accordance with subsection (3) of this section are deemed misbranded.*
- (5) *Food products identified in subsection (56) of Section 1 of this Act and produced, processed, and labeled in accordance with subsection (3) of this section are acceptable*

*food products that may only be offered for sale by farmers markets, certified roadside stands, or on the processor's farm. These food products may be used in preparing and serving food.*

- (6) Food products identified in subsection (56) of Section 1 of this Act and labeled in accordance with subsection (3) of this section shall not be required to be tested in determining whether or not the food product is an acid food, acidified food product, formulated acid food product, or low-acid food.*
- (7) The processing facilities of a home-based processor may be inspected annually by the cabinet.*
- (8) A home-based processor shall be subject to food sampling and inspection if it is determined that its food product is misbranded pursuant to subsection (4) of this section or adulterated, or if a consumer complaint has been received.*
- (9) If the cabinet has reason to believe that an imminent health hazard exists it may invoke cessation of production until it deems that the hazardous situation has been addressed to the satisfaction of the cabinet.*

SECTION 3. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED TO READ AS FOLLOWS:

- (1) The secretary shall promulgate administrative regulations to accommodate the specific circumstances of home-based microprocessors. In order to protect public health while encouraging the marketing of home-processed foods, the administrative regulations shall include, at a minimum, standards for:
  - (a) Installation, design, location, and maintenance of toilet rooms;*
  - (b) Installation and maintenance of hand-washing facilities;*
  - (c) Manual and mechanical cleaning and sanitizing processes;*
  - (d) Installation and location of equipment;*
  - (e) Construction and covering of floors; and*
  - (f) Construction, materials, and maintenance of walls and ceilings.**
- (2) Food products that are produced or processed by a home-based microprocessor and in compliance with administrative regulations promulgated pursuant to subsection (1) of this section are acceptable food products that may only be offered for sale by farmers markets, certified roadside stands, or on the processor's farm. These food products may be used in preparing and serving food.*

SECTION 4. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED TO READ AS FOLLOWS:

- (1) The Kentucky Cooperative Extension Service shall develop, implement, and administer a program to train home-based microprocessors or personnel in compliance with 21 C.F.R. sec. 114.10.*
- (2) The cabinet shall evaluate and certify home-based microprocessors or personnel who have completed the pilot microprocessing program or the microprocessing program.*
- (3) The cabinet shall by June 30, 2003:
  - (a) Establish certification terms, conditions, and length of time the certification is valid;**



- (b) *Establish terms, conditions, and standards for recertification;*
  - (c) *Establish fees for certification and recertification; and*
  - (d) *Develop a certification document.*
- (4) *The cabinet and the Kentucky Cooperative Extension Service shall by June 30, 2003:*
- (a) *Develop an examination document;*
  - (b) *Establish examination subject matter;*
  - (c) *Establish criteria for program completion; and*
  - (d) *Establish fees for the pilot microprocessing program and the microprocessing program.*
- (5) *The certification document shall be made in triplicate, with one (1) copy given to the home-based microprocessor or personnel, one (1) copy given to the Kentucky Cooperative Extension Service, and one (1) copy given to the cabinet.*
- (6) *Upon completion of the program, home-based microprocessors and personnel shall be deemed to be certified and to have met the training requirements pursuant to 21 C.F.R. sec. 114.10.*

SECTION 5. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED TO READ AS FOLLOWS:

- (1) *The Kentucky Cooperative Extension Service shall establish and administer a pilot microprocessing program to train home-based microprocessors and personnel for supervising or giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls, and critical factors in acidification.*
- (2) *The pilot microprocessing program shall be established by August 1, 2003, and implemented no later than September 1, 2003. There shall be no less than four (4) program workshops offered to home-based microprocessors and personnel, and each shall be held in a separate and distinct geographical location within the state.*

**Approved March 12, 2003**