

217.015 Definitions for KRS 217.005 to 217.215.

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 KRS 217.136 and 217.137, "bread" or "enriched bread" also means breads that may include vegetables or fruit as an ingredient;
- (3) "Cabinet" means the Cabinet for Health and Family 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, chiropodists, 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 practice registered nurses as authorized in KRS 314.011 and 314.042, physician assistants when administering or prescribing pharmaceutical agents as authorized in KRS 311.858, and health care professionals who are residents of and actively practicing in a state other than Kentucky and who are licensed and have prescriptive authority under the professional licensing laws of another state, unless the person's Kentucky license has been revoked, suspended, restricted, or probated, in which case the terms of the Kentucky license shall prevail;
- (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, chiropody, 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 and Family 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;
- (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;
- (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;
- (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 KRS 217.136 to 217.139, "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; and
- (60) "Farmers market temporary food service establishment" means any temporary food service establishment operated by a farmer who is a member of the market which operates within the confines of a farmers market registered with the Kentucky Department of Agriculture for the direct-to-consumer marketing of Kentucky-grown farm products from approved sources for a period of time not to exceed two (2) days per week for any consecutive six (6) months period in a calendar year.

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History: Amended 2010 Ky. Acts ch. 85, sec. 41, effective July 15, 2010.-- Amended 2007 Ky. Acts ch. 97, sec. 1, effective March 23, 2007. -- Amended 2005 Ky. Acts ch. 99, sec. 512, effective June 20, 2005. -- Amended 2003 Ky. Acts ch. 42, sec. 1, effective June 24, 2003; and ch. 51, sec. 1, effective June 24, 2003. -- Amended 2002 Ky. Acts ch. 130, sec. 35, effective July 15, 2002. - Amended 2000 Ky. Acts ch. 361, sec. 17, effective July 14, 2000. -- Amended 1998 Ky. Acts ch. 7, sec. 1, effective February 19, 1998, retroactive to January 1, 1998; ch. 228, sec. 7, effective July 15, 1998; ch. 297, sec. 1, effective July 15, 1998; ch. 301, sec. 1, effective July 15, 1998; and ch. 426, sec. 456, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 342, sec. 5, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 458, sec. 1, effective July 13, 1990. -- Amended 1986 Ky. Acts ch. 12, sec. 4, effective July 15, 1986. --

Amended 1982 Ky. Acts ch. 247, sec. 10, effective July 15, 1982. -- Amended 1978 Ky. Acts ch. 179, sec. 4, effective June 17, 1978; and ch. 292, sec. 1, effective June 17, 1978. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(1), (10) and (11). - Created 1960 Ky. Acts ch. 247, sec. 2.