

1 AN ACT relating to tallow-based cosmetic products.

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

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

4 For the purposes of KRS 217.005 to 217.215:

5 (1) "Advertisement" means all representations, disseminated in any manner or by any
6 means, other than by labeling, for the purpose of inducing, or which are likely to
7 induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics;

8 (2) "Bread" and "enriched bread" mean only the foods commonly known and described
9 as white bread, white rolls, white buns, enriched white bread, enriched rolls, and
10 enriched white buns, as defined under the federal act. For the purposes of KRS
11 217.136 and 217.137, "bread" or "enriched bread" also means breads that may
12 include vegetables or fruit as an ingredient;

13 (3) "Cabinet" means the Cabinet for Health and Family Services or its designee;

14 (4) "Color" means but is not limited to black, white, and intermediate grays;

15 (5) "Color additive" means a material that:

16 (a) Is a dye, pigment, or other substance made by a process of synthesis or similar
17 artifice, or extracted, isolated, or otherwise derived, with or without
18 intermediate or final change of identity, from a vegetable, animal, mineral, or
19 other source. ~~If nothing in~~ This paragraph shall not be construed to apply to
20 any pesticide chemical, soil or plant nutrient, or other agricultural chemical
21 solely because of its effect in aiding, retarding, or otherwise affecting, directly
22 or indirectly, the growth or other natural physiological process of produce of
23 the soil and thereby affecting its color, whether before or after harvest; or

24 (b) When added or applied to a food, drug, or cosmetic, or to the human body or
25 any part thereof, is capable, alone or through reaction with another substance,
26 of imparting color. "Color additive" does not include any material that has
27 been or may in the future be exempted under the federal act;

- 1 (6) "Contaminated with filth" means any food, drug, device, or cosmetic that is not
2 securely protected from dust, dirt, and as far as may be necessary by all reasonable
3 means, from all foreign or injurious contaminants;
- 4 (7) "Cosmetic" means:
 - 5 (a) Articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into,
6 or otherwise applied to the human body or any part thereof for cleansing,
7 beautifying, promoting attractiveness, or altering the appearance; and
 - 8 (b) Articles intended for use as a component of those articles, except that the term
9 shall not include soap;
- 10 (8) "Device," except when used in subsection (48) of this section, KRS 217.035(6),
11 KRS 217.065(3), KRS 217.095(3), and KRS 217.175(10), means instruments,
12 apparatus, and contrivances, including their components, parts, and accessories,
13 intended:
 - 14 (a) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease
15 in man or other animals; or
 - 16 (b) To affect the structure or any function of the body of man or other animals;
- 17 (9) "Dispense" means to deliver a drug or device to an ultimate user or research subject
18 by or pursuant to the lawful order of a practitioner, including the packaging,
19 labeling, or compounding necessary to prepare the substance for that delivery;
- 20 (10) "Dispenser" means a person who lawfully dispenses a drug or device to or for the
21 use of an ultimate user;
- 22 (11) "Drug" means:
 - 23 (a) Articles recognized in the official United States pharmacopoeia, official
24 homeopathic pharmacopoeia of the United States, or official national
25 formulary, or any supplement to any of them;
 - 26 (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or
27 prevention of disease in man or other animals;

- 1 (c) Articles, other than food, intended to affect the structure or any function of the
- 2 body of man or other animals; and
- 3 (d) Articles intended for use as a component of any article specified in this
- 4 subsection but does not include devices or their components, parts, or
- 5 accessories;
- 6 (12) "Enriched," as applied to flour, means the addition to flour of vitamins and other
- 7 nutritional ingredients necessary to make it conform to the definition and standard
- 8 of enriched flour as defined under the federal act;
- 9 (13) "Environmental Pesticide Control Act of 1972" means the Federal Environmental
- 10 Pesticide Control Act of 1972, Pub. L. 92-516, and all amendments thereto;
- 11 (14) "Fair Packaging and Labeling Act" means the Fair Packaging and Labeling Act as it
- 12 relates to foods and cosmetics, 15 U.S.C. secs. 1451 et seq., and all amendments
- 13 thereto;
- 14 (15) "Federal act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. secs. 301
- 15 et seq., 52 Stat. 1040 et seq., or amendments thereto;
- 16 (16) "Filled milk" means any milk, cream, or skimmed milk, whether or not condensed,
- 17 evaporated, concentrated, frozen, powdered, dried, or desiccated, to which has been
- 18 added, or which has been blended or compounded with, any fat or oil other than
- 19 milk fat, except the fat or oil of contained eggs and nuts and the fat or oil of
- 20 substances used for flavoring purposes only, so that the resulting product is an
- 21 imitation or semblance of milk, cream, skimmed milk, ice cream mix, ice cream, or
- 22 frozen desserts, whether or not condensed, evaporated, concentrated, frozen,
- 23 powdered, dried, or desiccated, whether in bulk or in containers, hermetically
- 24 sealed or unsealed. This definition does not mean or include any milk or cream
- 25 from which no part of the milk or butter fat has been extracted, whether or not
- 26 condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has
- 27 been added any substance rich in vitamins, nor any distinctive proprietary food

1 compound not readily mistaken for milk or cream or for condensed, evaporated,
2 concentrated, powdered, dried, or desiccated milk or cream, if the compound is
3 prepared and designed for the feeding of infants or young children, sick or infirm
4 persons, and customarily used on the order of a physician, and is packed in
5 individual containers bearing a label in bold type that the contents are to be used for
6 those purposes; nor shall this definition prevent the use, blending, or compounding
7 of chocolate as a flavor with milk, cream, or skimmed milk, desiccated, whether in
8 bulk or in containers, hermetically sealed or unsealed, to or with which has been
9 added, blended or compounded no other fat or oil other than milk or butter fat;

10 (17) "Flour" means only the foods commonly known as flour, white flour, wheat flour,
11 plain flour, bromated flour, self-rising flour, self-rising white flour, self-rising
12 wheat flour, phosphated flour, phosphated white flour, and phosphated wheat flour,
13 defined under the federal act;

14 (18) "Food" means:

15 (a) Articles used for food or drink for man or other animals;

16 (b) Chewing gum; and

17 (c) Articles used for components of any such article;

18 (19) "Food additive" means any substance the intended use of which results or may be
19 reasonably expected to result, directly or indirectly, in its becoming a component or
20 otherwise affecting the characteristics of any food, including any substance
21 intended for use in producing, manufacturing, packing, processing, preparing,
22 treating, packaging, transporting, or holding food; and including any source of
23 radiation intended for any of these uses, if the substance is not generally
24 recognized, among experts qualified by scientific training and experience to
25 evaluate its safety, as having been adequately shown through scientific procedures
26 or, in the case of a substance used in a food prior to January 1, 1958, through either
27 scientific procedures or experience based on common use in food to be safe under

1 the conditions of its intended use; except that the term does not include:

2 (a) A pesticide chemical in or on a raw agricultural commodity;

3 (b) A pesticide chemical to the extent that it is intended for use or is used in the

4 production, storage, or transportation of any raw agricultural commodity;

5 (c) A color additive; or

6 (d) Any substance used in accordance with a sanction or approval granted prior to

7 the enactment of the Food Additives Amendment of 1958, pursuant to the

8 federal act; the Poultry Products Inspection Act, 21 U.S.C. secs. 451 et seq.;

9 or the Meat Inspection Act of 1907; and amendments thereto;

10 (20) "Food processing establishment" means any commercial establishment in which

11 food is manufactured, processed, or packaged for human consumption, but does not

12 include retail food establishments, home-based processors, or home-based

13 microprocessors;

14 (21) "Food service establishment" means any fixed or mobile commercial establishment

15 that engages in the preparation and serving of ready-to-eat foods in portions to the

16 consumer, including but not limited to: restaurants; coffee shops; cafeterias; short

17 order cafes; luncheonettes; grills; tea rooms; sandwich shops; soda fountains;

18 taverns; bars; cocktail lounges; nightclubs; roadside stands; industrial feeding

19 establishments; private, public or nonprofit organizations or institutions routinely

20 serving food; catering kitchens; commissaries; charitable food kitchens; or similar

21 places in which food is prepared for sale or service on the premises or elsewhere

22 with or without charge. It does not include food vending machines, establishments

23 serving beverages only in single service or original containers, or retail food stores

24 which only cut, slice, and prepare cold-cut sandwiches for individual consumption;

25 (22) "Food storage warehouse" means any establishment in which food is stored for

26 subsequent distribution;

27 (23) "Immediate container" does not include package liners;

- 1 (24) "Imminent health hazard" means a significant threat or danger to health that is
2 considered to exist when there is evidence sufficient to show that a product,
3 practice, circumstance, or event creates a situation that requires immediate
4 correction or cessation of operation to prevent illness or injury based on:
5
 - 6 (a) The number of potential illnesses or injuries; or
 - 7 (b) The nature, severity, and duration of the anticipated illness or injury;
- 8 (25) "Interference" means threatening or otherwise preventing the performance of lawful
9 inspections or duties by agents of the cabinet during all reasonable times of
operation;
- 10 (26) "Label" means a display of written, printed, or graphic matter upon the immediate
11 container of any article; and a requirement made by or under authority of KRS
12 217.005 to 217.215 that any word, statement, or other information appearing on the
13 label shall not be considered to be complied with unless the word, statement, or
14 other information also appears on the outside container or wrapper, if any there be,
15 of the retail package of the article, or is easily legible through the outside container
16 or wrapper;
- 17 (27) "Labeling" means all labels and other written, printed, or graphic matter:
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 - 19 (a) Upon an article or any of its containers or wrappers; or
 - 20 (b) Accompanying the article;
- 21 (28) "Legend drug" means a drug defined by the Federal Food, Drug and Cosmetic Act,
22 as amended, and under which definition its label is required to bear the statement
23 "Caution: Federal law prohibits dispensing without prescription.";
- 24 (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;
- 25 (30) "New drug" means:
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 - 27 (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;

10 (32) "Person" means an individual, firm, partnership, company, corporation, trustee,
11 association, or any public or private entity;

12 (33) "Pesticide chemical" means any substance that alone in chemical combination, or in
13 formulation with one or more other substances, is an "economic poison" within the
14 meaning of the Federal Insecticide, Fungicide and Rodenticide Act and
15 amendments thereto, and that is used in the production, storage, or transportation of
16 raw agricultural commodities;

17 (34) "Poultry Products Inspection Act" means the Federal Poultry and Poultry Products
18 Inspection Act, 21 U.S.C. secs. 451 et seq., Pub. L. 85-172, 71 Stat. 441, and any
19 amendments thereto;

20 (35) "Practitioner" means medical or osteopathic physicians, dentists, chiropodists, and
21 veterinarians who are licensed under the professional licensing laws of Kentucky to
22 prescribe and administer drugs and devices. "Practitioner" includes optometrists
23 when administering or prescribing pharmaceutical agents authorized in KRS
24 320.240(12) to (14), advanced practice registered nurses as authorized in KRS
25 314.011 and 314.042, physician assistants when administering or prescribing
26 pharmaceutical agents as authorized in KRS 311.858, and health care professionals
27 who are residents of and actively practicing in a state other than Kentucky and who

1 are licensed and have prescriptive authority under the professional licensing laws of
2 another state, unless the person's Kentucky license has been revoked, suspended,
3 restricted, or probated, in which case the terms of the Kentucky license shall
4 prevail;

5 (36) "Prescription" means a written or oral order for a drug or medicine, or combination
6 or mixture of drugs or medicines, or proprietary preparation, that is signed, given,
7 or authorized by a medical, advanced practice registered nurse, dental, chiropody,
8 veterinarian, or optometric practitioner, and intended for use in the diagnosis, cure,
9 mitigation, treatment, or prevention of disease in man or other animals;

10 (37) "Prescription blank" means a document that conforms with KRS 217.216 and is
11 intended for prescribing a drug to an ultimate user;

12 (38) "Raw agricultural commodity" means any food in its raw or natural state, including
13 all fruits that are washed, colored, or otherwise treated in their unpeeled natural
14 form prior to marketing;

15 (39) "Retail food establishment" means any food service establishment, retail food store,
16 or a combination of both within the same establishment;

17 (40) "Retail food store" means any fixed or mobile establishment where food or food
18 products, including prepackaged, labeled sandwiches or other foods to be heated in
19 a microwave or infrared oven at the time of purchase, are offered for sale to the
20 consumer, and intended for off-premises consumption, but does not include
21 establishments which handle only prepackaged, snack-type, nonpotentially
22 hazardous foods, markets that offer only fresh fruits and vegetables for sale, food
23 service establishments, food and beverage vending machines, vending machine
24 commissaries, food processing establishments, or home-based processors;

25 (41) "Salvage distributor" means a person who engages in the business of distributing,
26 peddling, or otherwise trafficking in any salvaged merchandise;

27 (42) "Salvage processing plant" means an establishment operated by a person engaged in

1 the business of reconditioning, labeling, relabeling, repackaging, recoopering,
2 sorting, cleaning, culling or who by other means salvages, sells, offers for sale, or
3 distributes for human or animal consumption or use any salvaged food, beverage,
4 including beer, wine and distilled spirits, vitamins, food supplements, dentifrices,
5 cosmetics, single-service food containers or utensils, containers and packaging
6 materials used for foods and cosmetics, soda straws, paper napkins, or any other
7 product of a similar nature that has been damaged or contaminated by fire, water,
8 smoke, chemicals, transit, or by any other means;

9 (43) "Second or subsequent offense" has the same meaning as it does in KRS 218A.010;

10 (44) "Secretary" means the secretary of the Cabinet for Health and Family Services;

11 (45) "Temporary food service establishment" means any food service establishment
12 which operates at a fixed location for a period of time, not to exceed fourteen (14)
13 consecutive days;

14 (46) "Traffic" has the same meaning as it does in KRS 218A.010;

15 (47) "Ultimate user" has the same meaning as it does in KRS 218A.010;

16 (48) If an article is alleged to be misbranded because the labeling is misleading, or if an
17 advertisement is alleged to be false because it is misleading, in determining whether
18 the labeling or advertisement is misleading, there shall be taken into account,
19 among other things, not only representations made or suggested by statement, word,
20 design, device, sound, or in any combination thereof, but also the extent to which
21 the labeling or advertisement fails to reveal facts that are material in the light of the
22 representations or material with respect to consequences which may result from the
23 use of the article to which the labeling or advertisement relates under the conditions
24 of use prescribed in the labeling or advertisement thereof or under the conditions of
25 use as are customary or usual;

26 (49) The representation of a drug in its labeling or advertisement as an antiseptic shall be
27 considered to be a representation that it is a germicide, except in the case of a drug

1 purporting to be, or represented as, an antiseptic for inhibitory use as a wet
2 dressing, ointment, dusting powder, or other use involving prolonged contact with
3 the body;

4 (50) The provisions of KRS 217.005 to 217.215 regarding the selling of food, drugs,
5 devices, or cosmetics shall be considered to include the manufacture, production,
6 processing, packing, exposure, offer, possession, and holding of those articles for
7 sale, the sale, dispensing, and giving of those articles, and the supplying or applying
8 of those articles in the conduct of any food, drug, or cosmetic establishment;

9 (51) "Home" means a primary residence occupied by the processor, that contains only
10 two (2) ranges, ovens, or double-ovens, and no more than three (3) refrigerators
11 used for cold storage. This equipment shall have been designed for home use and
12 not for commercial use, and shall be operated in the kitchen within the residence;

13 (52) "Formulated acid food product" means an acid food in which the addition of a small
14 amount of low-acid food results in a finished equilibrium pH of 4.6 or below that
15 does not significantly differ from that of the predominant acid or acid food;

16 (53) "Acidified food product" means a low-acid food to which acid or acidic food is
17 added and which has a water activity value greater than 0.85, and a finished
18 equilibrium pH of 4.6 or below;

19 (54) "Low-acid food" means foods, other than alcoholic beverages, with a finished
20 equilibrium pH greater than 4.6, and a water activity value greater than 0.85;

21 (55) "Acid food" means foods that have a natural pH of 4.6 or below;

22 (56) "Home-based processor" means a person who in his or her home, produces or
23 processes **tallow-based cosmetic products or** non-potentially hazardous foods,
24 including but not limited to dried herbs, spices, nuts, candy, dried grains, whole
25 fruit and vegetables, mixed-greens, jams, jellies, sweet sorghum syrup, preserves,
26 fruit butter, bread, fruit pies, cakes, or cookies, and who has a gross income of no
27 more than sixty thousand dollars (\$60,000) annually from the sale of the products;

1 (57) "Home-based microprocessor" means a farmer who, in the farmer's home or
2 certified or permitted kitchen, produces or processes foods, including but not
3 limited to acid foods, formulated acid food products, acidified food products, or
4 low-acid canned foods, and who has a gross income of no more than sixty thousand
5 dollars (\$60,000) annually from the sale of the product;

6 (58) "Certified" means any person or home-based microprocessor who:

7 (a) Has attended the Kentucky Cooperative Extension Service's microprocessing
8 program or pilot microprocessing program and has been identified by the
9 Kentucky Cooperative Extension Service as having satisfactorily completed
10 the prescribed course of instruction; or

11 (b) Has attended some other school pursuant to 21 C.F.R. sec. 114.10;

12 (59) "Farmer" means a person who is a resident of Kentucky and owns or rents
13 agricultural land pursuant to subsection (9) of KRS 132.010 or horticultural land
14 pursuant to subsection (10) of KRS 132.010. For the purposes of KRS 217.136 to
15 217.139, "farmer" also means any person who is a resident of Kentucky and has
16 grown the primary horticultural and agronomic ingredients used in the home-based
17 micropocessed products which they have produced; and

18 (60) "Farmers market temporary food service establishment" means any temporary food
19 service establishment operated by a farmer who is a member of the market which
20 operates within the confines of a farmers market registered with the Kentucky
21 Department of Agriculture for the direct-to-consumer marketing of Kentucky-
22 grown farm products from approved sources for a period of time not to exceed two
23 (2) days per week for any consecutive six (6) months period in a calendar year.

24 ➔ Section 2. KRS 217.136 is amended to read as follows:

25 (1) A home-based processor shall be exempt from KRS 217.035, ~~and~~ 217.037, and
26 217.095 if the following conditions are met:

27 (a) All finished product containers are clean, sanitary, and properly labeled

1 pursuant to subsection (3) of this section;

2 (b) All home-processed foods or tallow-based cosmetic products produced under
3 this exemption are neither adulterated nor misbranded pursuant to subsection
4 (4) of this section; and

5 (c) All glass containers for jams, jellies, preserves, fruit butter, and similar
6 products are provided with suitable rigid metal covers.

7 (2) A home-based processor shall not produce or process for sale acid foods, acidified
8 food products, formulated acid food products, or low-acid canned foods.

9 (3) A home-based processor shall label each of its food or cosmetic products and
10 include the following information on the label of each of its food or cosmetic
11 products:

12 (a) The name and address of the home-based processing operation;

13 (b) The common or usual name of the food or cosmetic product;

14 (c) The ingredients of the food or cosmetic product, in descending order of
15 predominance by weight;

16 (d) The net weight and volume of the food or cosmetic product by standard
17 measure, or numerical count;

18 (e) The following statement in ten (10) point type: "This product is home-
19 produced and processed"; and

20 (f) The date the product was processed.

21 (4) Food or cosmetic products identified in KRS 217.015(56) and not labeled in
22 accordance with subsection (3) of this section are deemed misbranded.

23 (5) Food or cosmetic products identified in KRS 217.015(56) and produced, processed,
24 and labeled in accordance with subsection (3) of this section are acceptable food or
25 cosmetic products that may only be offered for sale directly to consumers within
26 this state, including from the home-based processor's home, whether by pick-up or
27 delivery, at a market, roadside stand, community event, or online. These food

1 products may be used in preparing and serving food.

2 (6) Food products identified in KRS 217.015(56) and labeled in accordance with
3 subsection (3) of this section shall not be required to be tested in determining
4 whether or not the food product is an acid food, acidified food product, formulated
5 acid food product, or low-acid food.

6 (7) The processing facilities of a home-based processor may be inspected annually by
7 the cabinet.

8 (8) A home-based processor shall be subject to product~~food~~ sampling and inspection
9 if it is determined that its ~~food~~product is misbranded pursuant to subsection (4) of
10 this section or adulterated, or if a consumer complaint has been received.

11 (9) If the cabinet has reason to believe that an imminent health hazard exists it may
12 invoke cessation of production until it deems that the hazardous situation has been
13 addressed to the satisfaction of the cabinet.

14 (10) The cabinet shall promulgate administrative regulations to further delineate which
15 food or cosmetic products are subject to the definition of home-based processor, as
16 defined in KRS 217.015(56).

17 (11) ~~No later than January 1, 2020, the cabinet shall develop and implement a~~
18 ~~registration system for home based processors.~~

19 (12) ~~Beginning January 1, 2020,~~ A home-based processor shall be registered with the
20 cabinet and include the following information:

21 (a) The name of the home-based processor and the physical address where
22 production or processing will occur; and

23 (b) A listing of the food or cosmetic products to be produced or processed.