

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

902 KAR 45:160. Kentucky food and cosmetic processing, packaging, storage, and distribution operations.

RELATES TO: KRS 13B, 194A.005, 217.005 - 217.205, 271.215, 217.290 - 217.390, 217.990 - 217.992, 318.130, 21 C.F.R. Part 1, 7, 70, 73, 74, 81, 82, 100 - 102, 104 - 107, 108 Subpart B, 109, 113, 114, 117, 120, 123, 129, 130, 133, 135 - 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163 - 166, 168, 169, 170, 172 - 178, 180 - 189, 21 U.S.C. 321, 343-345, 373, 374, 374a

STATUTORY AUTHORITY: KRS 194A.050(1), 211.090(3), 211.180(1), 217.125(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) and 217.125(1) authorize the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of KRS 217.005 to 217.215. The secretary is authorized to promulgate administrative regulations consistent with those promulgated under the federal act and the Fair Packaging and Labeling Act~~[to regulate food processing, packaging, storage, and distribution operations]~~. This administrative regulation establishes procedures and requirements for food and cosmetic processing, packaging, storage, and distribution operations for the purpose of protecting public health.

Section 1. Definitions. (1) "Adulterated" is defined by KRS 217.025.

(2) "Cabinet" is defined by KRS 194A.005(1).

(3) "Food processing establishment" is defined by KRS 217.015(20).

(4) "Food storage warehouse" is defined by KRS 217.015(22).

(5) "Imminent health hazard" is defined by KRS 217.015(24).

(6) "Misbranded" is defined by KRS 217.035.

(7) "No Action Indicated" or "NAI" means a plant inspection classification that indicates the firm has no violating condition or that only a minor violation was noted at the time of inspection.

(8) "Official Action Indicated" or "OAI" means a plant inspection classification that indicates a condition noted during the inspection was significant enough to pose an imminent health hazard or was an uncorrected VAI condition on a previous inspection.

(9) "Plant" means a food processing establishment, cosmetic processing establishment, or a food storage warehouse.

(10) "Ready-to-eat" means food that is in a form that is edible without washing, cooking, or additional preparation by the food plant or the consumer to achieve food safety, and is expected to be consumed in that form.

(11) "Specialized processes" means foods processed under 21 C.F.R. Parts 113, 114, 120, and 123.

(12) "State Plumbing Code" means the code established by KRS Chapter 318 and 815 KAR Chapter 20.

(13)~~(14)~~ "Voluntary Action Indicated" or "VAI" means a plant inspection classification that indicates a condition was noted during the inspection that is in violation of this administrative regulation but was not significant enough to pose an imminent health hazard.

Section 2. Applicability. (1) Except as provided in subsection (2) of this section, a plant shall comply with the following federal requirements:

- (a) 21 U.S.C. 373, Records;
- (b) 21 C.F.R. 1.20 - 1.24, General labeling requirements;
- (c) 21 C.F.R. 7.1 - 7.13, General [~~enforcement policy~~] provisions;
- (d) 21 C.F.R. 7.40 - 7.59, Food recalls provisions;
- (e) 21 C.F.R. 70.20 - 70.25, Packaging and labeling requirements;
- (f) 21 C.F.R. 73.1 - 73.615, Listing of food color additives exempt from certification;
- (g) 21 C.F.R. 74.101 - 74.706, Listing of food color additives subject to certification;
- (h) 21 C.F.R. Part 81, General specifications and general restrictions for provisional color additives for use in foods, drugs, and cosmetics;
- (i) 21 C.F.R. 82.3 - 82.706, Listing of certified provisionally listed food colors and specifications;
- (j) 21 C.F.R. 100.155, Salt and iodized salt;
- (k) 21 C.F.R. Part 101, Food labeling;
- (l) 21 C.F.R. Part 102, Common or usual name for nonstandardized~~[non-standardized]~~ foods;
- (m) 21 C.F.R. Part 104, Nutritional quality guidelines for foods;
- (n) 21 C.F.R. Part 105, Foods for special dietary use;
- (o) 21 C.F.R. Part 106, Infant formula quality control procedures;
- (p) 21 C.F.R. Part 107, Infant formula;
- (q) 21 C.F.R. 108 Subpart B, Specific requirements and conditions for exemption from or compliance with an emergency permit;
- (r) 21 C.F.R. Part 109, Unavoidable contaminants in food for human consumption and food packaging materials;
- (s) 21 C.F.R. Part 113, Low acid foods;
- (t) 21 C.F.R. Part 114, Acidified foods;
- (u) 21 C.F.R. Part 117, Hazard analysis and critical control point (HACCP) systems;
- (v) 21 C.F.R. Part 120, Hazard analysis and critical control point (HACCP) systems;
- (w) 21 C.F.R. Part 123, Fish and fishery products;
- (x) 21 C.F.R. Part 129, Processing and bottling of bottled drinking water;
- (y) 21 C.F.R. Part 130, Food standards general;
- (z) 21 C.F.R. 133.10, 133.124, 133.125, 133.167 – 133.169, 133.171, 133.173 – 133.176, 133.179 – 133.180, Cheeses and related cheese products;
- (aa) 21 C.F.R. Part 135, Frozen desserts;
- (bb) 21 C.F.R. Part 136, Bakery products;
- (cc) 21 C.F.R. Part 137, Cereal flours and related products;
- (dd) 21 C.F.R. Part 139, Macaroni and noodle products;
- (ee) 21 C.F.R. Part 145, Canned fruits;
- (ff) 21 C.F.R. Part 146, Canned fruit juices;
- (gg) 21 C.F.R. Part 150, Fruit butters, jellies, preserves, and related products;
- (hh) 21 C.F.R. Part 152, Fruit pies;
- (ii) 21 C.F.R. Part 155, Canned vegetables;
- (jj) 21 C.F.R. Part 156, Vegetable juices;
- (kk) 21 C.F.R. Part 158, Frozen vegetables;
- (ll) 21 C.F.R. Part 160, Eggs and egg product;
- (mm) 21 C.F.R. Part 161, Fish and shellfish;
- (nn) 21 C.F.R. Part 163, Cacao products;
- (oo) 21 C.F.R. Part 164, Tree nut and peanut products;
- (pp) 21 C.F.R. Part 165, Beverages;
- (qq) 21 C.F.R. Part 166, Margarine;
- (rr) 21 C.F.R. Part 168, Sweeteners and table syrups;

(ss) 21 C.F.R. Part 169, Food dressings and flavorings;
(tt) 21 C.F.R. Part 170, Food additives;
(uu) 21 C.F.R. Part 172, Food additives permitted for direct addition to food for human consumption;
(vv) 21 C.F.R. Part 173, Secondary direct food additives permitted in food for human consumption;
(ww) 21 C.F.R. Part 174, Indirect food additives: general;
(xx) 21 C.F.R. Part 175, Indirect food additives: adhesives and components of coatings;
(yy) 21 C.F.R. Part 176, Indirect food additives: paper and paperboard components;
(zz) 21 C.F.R. Part 177, Indirect food additives: polymers;
(aaa) 21 C.F.R. Part 178, Indirect food additives: adjuvants, production aids, and sanitizers;
(bbb) 21 C.F.R. Part 180, Food additives permitted in food or in contact with food on an interim basis pending additional study;
(ccc) 21 C.F.R. Part 181, Prior sanctioned food ingredients;
(ddd) 21 C.F.R. Part 182, Substances generally recognized as safe;
(eee) 21 C.F.R. Part 184, Direct food substances affirmed as generally recognized as safe;
(fff) 21 C.F.R. Part 186, Indirect food substances affirmed as generally recognized as safe;
(ggg) 21 C.F.R. Part 189, Substances prohibited from use in human food; and
(hhh) 21 U.S.C. 321, 343 to 345, 374, 374a, Nutritional and food allergen labeling requirements.

(2) The following federal regulations shall not apply:

- (a) 21 C.F.R. 101.69;
- (b) 21 C.F.R. 101.108;
- (c) 21 C.F.R. 102.19;
- (d) 21 C.F.R. 106.120;
- (e) 21 C.F.R. 107.200 - 107.280;
- (f) 21 C.F.R. 120.14;
- (g) 21 C.F.R. 123.12;
- (h) 21 C.F.R. 130.5 - 130.6;
- (i) 21 C.F.R. 130.17;
- (j) 21 C.F.R. 170.6;
- (k) 21 C.F.R. 170.15; and
- (l) 21 C.F.R. 170.17.

Section 3. Permits. (1) Before operating, a food or cosmetic manufacturing or processing plant, [fœd] packaging plant, [fœd] storage warehouse, or [fœd] distribution warehouse shall obtain a permit from the cabinet in accordance with KRS 217.125.

(2) Application for a permit shall be made on a Form DFS-260, Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, and shall be submitted to the cabinet with the annual fee established by 902 KAR 45:180[140].

(3) A permit for food or cosmetic manufacturing or processing plant, [fœd] packaging, [fœd] storage, or [fœd] distribution shall only be issued:

- (a) In the name of the applicant;
- (b) For the location identified in the application; and
- (c) For a firm that is in compliance with this administrative regulation and KRS 217.005 - 217.215.

(4) A permit shall:

- (a) Be posted in a conspicuous place in the firm;
- (b) Expire on December 31 of each year; and

(c) Be renewed in accordance with KRS 217.125(12) [and] by submitting the form and fee required by subsection (2) of this section.

(5) Failure to apply for or renew a permit to operate a food or cosmetic manufacturing or processing plant, packaging plant, storage warehouse, or distribution warehouse[plant] shall result in the cabinet issuing a Food or Cosmetic Manufacturing Plant Enforcement Notice (DFS-263) to cease operation.

(6) Food processing plants shall be classified by the highest risk level of the food processed.

(a) A high risk food plant:

1. Is engaged in international, interstate, statewide, or regional distribution; and

2. Uses one (1) or all of the following manufacturing processes:

a. Time and temperature controlled foods that are ready-to-eat;

b. High risk foods that are considered ready-to-eat; or

c. Foods that require specialized processes to decrease risk potential.

(b) A medium risk food plant processes foods that are either ready-to-eat foods or potentially hazardous foods, but not both.

(c) A low risk food plant processes foods that are not time and temperature controlled.

Section 4. Plan Review. (1) Approval shall be obtained from the cabinet or its local health department agent prior to beginning work, if:

(a) A plant is constructed, remodeled, or altered;

(b) A plant's plumbing is relocated;

(c) Additional plumbing is added to a plant; or

(d) An existing structure is converted for use as a plant.

(2) To obtain approval, an applicant shall submit plans and specifications for the construction, remodeling, or alteration to the local health department in the county in which the construction, remodeling, or alteration will take place.

(3) Plans shall be prepared to show:

(a) Equipment layout;

(b) Size;

(c) Location and type of facilities; and

(d) Plumbing riser diagram.

Section 5. Construction and Maintenance. (1) The floor of the [foed] preparation, [foed] storage, and utensil washing area, walk-in refrigerator, dressing room, locker room, toilet room, and vestibule shall be:

(a) Smooth;

(b) Durable;

(c) Non-absorbent; and

(d) Easily cleaned.

(2) Floors shall be cleaned and maintained.

(3) A juncture of a wall with a floor shall be covered and sealed.

(4) The juncture between the wall and floor shall be tight-fitting.

(5)(a) A floor drain shall be provided in a floor that is water flushed for cleaning or that receives discharge of water or other fluid waste from equipment.

(b) Floors shall be graded to drain all parts of the floor.

(6) Drip or condensate from fixtures, ducts, and pipes shall not contaminate food, food-contact surfaces, or food-packaging materials.

(7) Mats shall be:

(a) Non-absorbent;

- (b) Slip resistant; and
- (c) Easily cleaned.
- (8) Mats shall not be used as storage racks.
- (9) Exposed utility service lines and pipes shall be installed to prevent tripping hazards and cleaning obstructions.
- (10) Walls and ceilings, including doors, windows, skylights, and similar closures, shall be maintained in good repair.
- (11) Walls and ceilings of all ~~[food]~~ preparation and warewashing~~[ware washing]~~ areas shall be:
 - (a) Smooth;
 - (b) Non-absorbent; and
 - (c) Easily cleaned.
- (12) Studs, joists, and rafters shall not be exposed in:
 - (a) Walk-in-refrigerators;
 - (b) ~~[Food]~~ Preparation areas; and
 - (c) Warewashing~~[Ware washing]~~ areas.
- (13) Doors shall be:
 - (a) Solid;
 - (b) Tight-fitting; and
 - (c) Closed, except during cleaning or maintenance.
- (14) Light fixtures, vent covers, wall-mounted fans, and similar equipment attached to walls or ceilings shall be kept clean and maintained in good repair.
- (15) Aisles and working spaces shall be:
 - (a) Unobstructed; and
 - (b) Of a width to permit employees to perform their duties and protect against contaminating food, cosmetics, or ~~[food-contact]~~ surfaces with clothing or by personal contact.
- (16) Lighting shall be provided in:
 - (a) Hand washing~~[Hand washing]~~ areas;
 - (b) Dressing and locker rooms;
 - (c) Toilet rooms;
 - (d) Areas where food or cosmetics are~~[is]~~ examined, processed, or stored; and
 - (e) Areas where equipment or utensils are cleaned.
- (17) Lighting, glass fixtures, and skylights suspended over exposed ~~[food or food]~~ packaging materials shall be made of safety glass or otherwise shielded to protect against ~~[food]~~ contamination in case of breakage.
- (18) Ventilation or exhaust control equipment shall be provided to minimize odors or vapors in areas where odors or vapors may contaminate food.
- (19) Fans and other air-blowing equipment shall be located and operated in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
- (20) Protection against pests shall be provided.

Section 6. Water Supply. (1) The water supply shall be:

- (a) Potable;
 - (b) Of sufficient quantity to meet plant needs; and
 - (c) From an approved public water system, if available.
- (2) If a public water system is not available, the supply for the plant shall be approved pursuant to 401 KAR Chapters 8 and 11.

(3) If a community public water system later becomes available and has the capacity to serve the facility, connections may be made to it. The non-community water supply shall then be discontinued and inactivated.

(4) Hot and cold running water under pressure shall be provided in all areas where it is needed for:

(a) Processing food or cosmetics;

(b) Cleaning equipment, utensils, and [~~food-~~]packaging materials; and

(c) Employee sanitary facilities.

(5) Bottled water plants shall have their water supply system designed, approved, and operated in accordance with 401 KAR 8:700.

Section 7. Plumbing. (1) All plumbing shall comply with the minimum fixture requirements, and be sized, installed, and maintained in accordance with the State Plumbing Code.

(2) All utensils used in food or cosmetic processing that are not a part of a clean-in-place operation shall be washed, rinsed, and sanitized in:

(a) A permanently plumbed three (3) compartment sink; or

(b) A commercial dishwasher installed and operated in compliance with the State Plumbing Code and the manufacturer's instructions.

(3) If a three (3) compartment sink is utilized, the sink compartments shall be large enough to permit the accommodation of the equipment and utensils and each compartment of the sink shall be supplied with hot and cold potable running water under pressure.

(4) Clean-in-place equipment shall be cleaned or sanitized according to manufacturer instructions and industry best practices for the commodity being processed.

(5) Written sanitation procedures shall be maintained for each type of clean-in-place equipment.

(6) A service sink or curbed cleaning facility with a drain that allows for disposal of mop and cleaning solution water shall be provided.

(7) A person, firm, or corporation shall not construct, install, or alter any plumbing without having procured a plumbing construction permit from the Department of Housing, Buildings and Construction, under KRS Chapter 318.

Section 8. Sewage Disposal. (1) All sewage shall be disposed of into a public sewerage system, if available.

(2) If a public sewerage system is not available, disposal shall be made into a private system designed, constructed, and operated pursuant to the requirements of 401 KAR Chapter 5 or 902 KAR 10:085.

(3) If a public sewerage system becomes available, connection shall be made and the private sewerage system shall be discontinued.

Section 9. Toilet Facilities. Toilet facilities shall meet the fixture and construction requirements of KRS Chapter 318 and the State Plumbing Code.

Section 10. Hand Washing Facilities. (1) Hand washing[~~Hand-washing~~] facilities shall be installed in

accordance with KRS Chapter 318 and the State Plumbing Code where:

(a) Food or cosmetic are[is] prepared;

(b) Utensils are washed; and

(c) Sanitary practices require employees to wash and sanitize their hands.

(2) All hand washing facilities shall be provided with:

- (a) Soap;
- (b) Disposable hand drying towels or mechanical hand drying devices; and
- (c) Non-absorbent waste receptacles.
- (3) Hand sanitizer shall not be used instead of hand washing.
- (4) Lavatories used for hand washing shall not be used for food or cosmetic preparation or for washing equipment or utensils.
- (5) Lavatories, soap dispensers, and hand drying devices shall be kept clean and maintained.

Section 11. Food Transportation. (1) Vehicles used for the transportation of food shall be maintained and loaded in a manner to prevent cross-contamination of food.

- (2) Vehicles that transport refrigerated food shall be capable of maintaining:
 - (a) Frozen food in a frozen state; and
 - (b) Refrigerated foods at forty-five (45) degrees Fahrenheit or below.

Section 12. Inspection Frequencies. (1) The cabinet shall assign an inspection frequency to each food processing[~~manufacturing~~] plant based upon the degree of risk associated with the commodity processed, packaged, stored, or distributed by the plant.

- (2) The cabinet shall assign the inspection frequencies as follows:
 - (a) High risk food plants shall be inspected no less than once every 1,080 days;
 - (b) Medium risk food plants shall be inspected no less than once every 1,260 days; and
 - (c) Low risk food plants shall be inspected no less than once every 1,440 days.
- (3) Cosmetic manufacturing plants shall be inspected no less than once every 1,440 days.
- (4) The cabinet shall conduct additional inspections as necessary for enforcement pursuant to this administrative regulation.

Section 13. Violations. (1) If a plant has committed a violation of this administrative regulation, an opportunity to correct the violation shall be provided in accordance with the following classifications:

- (a) NAI - No changes in the inspection frequency are warranted under this classification;
 - (b) VAI - A follow-up inspection is warranted within a period of time not to exceed ninety (90) days to determine if the violation causing this classification has been corrected; or
 - (c) OAI - A follow-up inspection shall be conducted within a period of time not to exceed forty-five (45) days to determine if the violation causing the classification has been corrected. A plant may also be classified as OAI if it continually fails to correct a violation previously classified under a VAI designation or if an imminent health hazard is noted during an inspection.
- (2) Upon completion of the inspection, a recommended classification of NAI, VAI, or OAI and the timeframe for correction of the violation shall be specified on a DFS-220, Food or Cosmetic Plant Inspection Report.
- (3) If, during a follow-up inspection, the violation noted on the previous inspection has not been corrected within the timeframe specified by the cabinet, the cabinet shall:
- (a) Extend the timeframe for corrective action if the cabinet determines that progress towards compliance has been made; or
 - (b) Initiate enforcement provisions pursuant to Section 17 of this administrative regulation.

Section 14. Food or Cosmetic Plant Environmental Sampling. The cabinet shall collect an environmental sample in an area of the plant as necessary for the enforcement of this administrative regulation.

Section 15. Examination and Detention of Foods and Cosmetics. (1) The cabinet shall examine and collect samples of food or cosmetic as often as necessary for the enforcement of this administrative regulation.

(2) If a food or cosmetic is considered to be adulterated or misbranded, DFS-265, Food or Cosmetic Plant Quarantine-~~[F]~~Final Disposition Report, shall be issued to the permit holder or person in charge pursuant to KRS 217.115.

Section 16. Imminent Health Hazard and Notification Requirements. (1) The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard.

(2)(a) The permit holder shall notify the cabinet within twenty-four (24) hours of the knowledge of an imminent health hazard that cannot be controlled by immediate corrective action or if food, food contact equipment, ~~[or]~~ food packaging, cosmetic, or cosmetic packaging has become contaminated because of an imminent health hazard.

(b) Written notification to the cabinet shall be made by:

1. Email to CHFSDPHENV@KY.gov; or
2. Fax to 502-696-1882.

(3) If the cabinet has evidence that a plant has failed to act to correct an imminent health hazard, enforcement provisions shall be initiated pursuant to Section 17 of this administrative regulation.

Section 17. Enforcement Provisions. (1) If the cabinet has substantial reason to believe that a permit holder has failed to act to correct an imminent health hazard or if the permit holder or an authorized agent has interfered with the cabinet in the performance of its duties after its agents have duly and officially identified themselves, the cabinet shall immediately notify the permit holder using the DFS-263, Food or Cosmetic Plant Enforcement Notice and:

(a) Suspend the permit without a conference; or

(b) Suspend that portion of the plant operation affected by the imminent health hazard without a conference.

(2) If a permit suspension is due to an imminent health hazard, the permit holder may request a conference on a DFS-267, Request for Conference. A conference shall be granted as soon as practical, not to exceed seven (7) days from the receipt of the Request for Conference.

(3) In all other instances of violation of this administrative regulation, the cabinet shall serve the permit holder with a written notice specifying the violation and afford the holder an opportunity to correct.

(4) If a permit holder or operator has failed to comply with an OAI inspection notice within the timeframe granted, the cabinet shall issue a Notice of Intent to Suspend Permit on a DFS-263, Food or Cosmetic Plant Enforcement Notice.

(5) When a Notice of Intent to Suspend Permit is issued, the permit holder or operator shall be notified in writing that the permit shall be suspended at the end of ten (10) days following service of the notice, unless a written request for a conference is filed with the cabinet by the permit holder within the ten (10) day period.

(6) Any person whose permit has been suspended may make application on ~~a~~[Form] DFS-269, Application for Reinstatement, for a re-inspection for the purpose of reinstatement of the permit. Within seven (7) days following receipt of a written request, including a statement signed by the applicant that in his opinion the condition causing suspension of the permit has been corrected, the cabinet shall make an inspection, and if the inspection reveals that the condition causing suspension of the permit has been corrected, the permit shall be reinstated.

(7) For a plant that has had a suspended permit two (2) or more times within a five (5) year period, the cabinet shall initiate permit revocation proceedings. Prior to this action, the cabinet shall notify the permit holder in writing on a DFS-263, Food or Cosmetic Plant Enforcement Notice, stating the reasons for which the permit revocation is being sought and advising that the permit shall be permanently revoked at the end of ten (10) days following service of the notice, unless a request for an administrative hearing is filed with the cabinet pursuant to KRS Chapter 13B by the permit holder within the ten (10) day period.

(8) Notice provided for under this administrative regulation shall be deemed to have been properly served if:

(a) A copy of the inspection report or other notice has been delivered personally to the permit holder; or

(b) The notice has been sent by registered or certified mail, return receipt.

Section 18. Administrative Conferences. An administrative conference shall be conducted pursuant to 902 KAR 1:400.

Section 19. Administrative Hearings. An administrative hearing shall be conducted pursuant to KRS Chapter 13B.

Section 20. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "DFS-220, Food or Cosmetic Plant Inspection Report", 8/20[05/18];

(b) "DFS-260, Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant", 8/20[05/18];

(c) "DFS-263, Food or Cosmetic Plant Enforcement Notice", 8/20[05/18];

(d) "DFS-265, Food or Cosmetic Plant Quarantine-~~[F]~~Final Disposition Report", 8/20[05/18];

(e) "DFS-267, Request for Conference", 8/20[05/18]; and

(f) "DFS-269, Application for Reinstatement", 8/20[05/18].

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at Cabinet for Health and Family Services, Department for Public Health, Division of Public Health Protection and Safety, Food Safety Branch, 275 East Main Street, Frankfort, Kentucky 40602, Monday through Friday, 8 a.m. to 4:30 p.m.

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: December 4, 2020 at 9:28 a.m.

FILED WITH LRC: December 11, 2020 at 9:28 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on February 22, 2021, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by February 15, 2021, 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 virtually 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 February 28, 2021. Send written notification of intent to attend the public hearing or written comments on the pro-

posed 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: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes procedures and requirements for food processing, packaging, storage, and distribution operations for the purpose of protecting public health.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to ensure food processing and packaging activities, food storage and distribution facilities, and all other entities engaged in the manufacture and storage of food and food products are properly permitted, and facilities are constructed in a manner that protects public health.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217.125(2) prohibits a person from operating a food processing establishment, food storage warehouse, salvage distributor or salvage processing plant without obtaining an annual permit to operate from the cabinet. This administrative regulation incorporates the application form, outlines the inspection criteria, and incorporates the inspection form.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will ensure all food processing facilities, including facilities for food packaging materials, and food storage facilities are properly permitted and inspected.

(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: The amendment to this administrative regulation updates the cross reference citation for the food and cosmetic processing establishment fee schedule, adds requirements for cosmetic manufacturing facilities, and updates the material incorporated by reference.

(b) The necessity of the amendment to this administrative regulation: The fee schedule for food processing establishments was promulgated under a new administrative regulation, 902 KAR 45:180. The amendment to this administrative regulation is necessary to ensure the correct cross reference for the fees is listed. The incorporated by reference materials were updated to include reference to cosmetic manufacturing plants.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 217.125 authorizes the cabinet to promulgate regulations consistent with those promulgated under the federal act and the Fair Packaging and Labeling Act. Regulations promulgated may require permits to operate and include the provisions for regulating the issuance, suspension, and reinstatement of permits. KRS 211.180(1) authorizes the cabinet to regulate the safety of cosmetics. This administrative regulation establishes the permitting and inspection process for food processing plants, and adopts the federal standards by reference, and makes reference to include cosmetic manufacturing plants.

(d) How the amendment will assist in the effective administration of the statutes: The amendment to this administrative regulation will ensure all food processing plants, food storage warehouses, salvage distributors or salvage processing plants, and cosmetic manufactur-

ing plants are properly permitted and inspected. The permitting and inspection process will help to ensure the safety of manufactured food and food products, and cosmetics.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There are 1,072 food processing plants and seventy-seven (77) cosmetic manufacturers registered with the department.

(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: Food processing plants, food storage warehouses, salvage distributors or salvage processing plants, and cosmetic manufacturing plants are required to be in compliance with the applicable federal standards. Owners will need to be aware of the updated application form and submit the correct version of the form when renewing the application.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): There is no cost associated with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): All regulated entities will be able to ensure the food and food products have been properly inspected and are safe for human consumption. Cosmetic manufacturers will be able to ensure their products have been properly inspected and are safe for human usage.

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

(a) Initially: This is an ongoing program, there are no initial costs associated with this amendment.

(b) On a continuing basis: The Food Manufacturing Program within the Food Safety Branch costs approximately \$1,080,000 each year.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Food Manufacturing Program is funded through a mix of state and federal funds, and revenue received from the fees established in 902 KAR 45:180.

(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: An increase in fees or funding is not necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. There are no fees established in this administrative regulation.

(9) TIERING: Is tiering applied? Tiering is not applied. While food processing establishments are ranked based on the risk level of the foods processed, the provisions of this administrative regulation are applied equally to all establishments.

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? The Food Safety Branch within the Department for Public Health will be impacted by this amendment.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.050(1), 211.090(3), 211.180(1), and 217.125(1).

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.

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? This administrative regulation does not generate revenue.

(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? This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year? The Food Manufacturing Program within the Food Safety Branch costs approximately \$1,080,000 each year.

(d) How much will it cost to administer this program for subsequent years? The Food Manufacturing Program within the Food Safety Branch will continue to cost approximately \$1,080,000 each year.

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. The federal Food, Drug, and Cosmetic Act; 21 U.S.C. 321, 343-345, 373, 374, 374a; and 21 C.F.R.

2. State compliance standards. This administrative regulation adopts the federal requirements for food processing, packaging, storage, and distribution operations. The Food Safety Branch in the Department for Public Health is directed by the federal Food and Drug Administration (FDA) on which code of federal regulation to adopt to be in full compliance with the FDA food manufacturing standards.

3. Minimum or uniform standards contained in the federal mandate. KRS 217.125(1) authorizes the cabinet to promulgate regulations consistent with those promulgated under the federal act and the Fair Packaging and Labeling Act.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. There are no different, stricter, or additional responsibilities or requirements.