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

902 KAR 45:180. Permits and fees for food, cosmetic, and dietary supplement manufacturing and processing plants, [food] storage warehouses, [salvage processors] [and distributors, cosmetic manufacturers,] and certificate of free sale.

RELATES TO: KRS [217.015,]217.025, 217.035, 217.037, 217.045, 217.085, 217.095, 217.992[217.155], 21 C.F.R. Parts 111, 113, 114, 120, 123

STATUTORY AUTHORITY: KRS 211.180(2)(b), 217.125(1), (2)

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of reasonable fees to be paid by food, cosmetic, and dietary supplement processing plants, and[food] storage warehouses[, salvage distributors, salvage processing plants, and cosmetic manufacturers] for permits to operate and for inspection activities carried out by the cabinet. KRS 217.992 establishes the penalties applicable to those who violate the provisions of KRS 217.005 to 217.215. This administrative regulation establishes the schedule of fees including the penalties assessed for noncompliance.

Section 1. Definitions.

(1) "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.

(2) "Specialized processes" means foods processed under 21 C.F.R. Parts 113, 114, 120, or 123, or require specialized food safety controls beyond the standard good manufacturing practices.

(3) "Time and temperature-controlled foods" means food that requires time and temperature control for safety to limit pathogenic microorganism growth or toxin formation.

Section 2. Classification. Food manufacturing, packaging, storage, and distribution operations[processing and storage facilities] shall be classified by the highest risk level of the food processed or stored.

(1) A business[facility] shall be classified as a high-risk[high risk] food plant or risk level 1 if the business[facility]:

(a) Is engaged in international, interstate, statewide, or regional distribution; and

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

1. Time and temperature-controlled[temperature controlled] foods that are ready-to-eat;

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

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

(2) A business[facility] shall be classified as a medium-risk[medium risk] food plant or risk level 2 if the business[facility] processes foods that are either ready-to-eat foods or time and temperature-controlled[potentially hazardous] foods, but not both.

(3) A business[facility] shall be classified as a low-risk[low risk] food plant or risk level 3 if the business[facility] processes foods that are not time and temperature controlled.

(4) A dietary supplement manufacturer or dietary supplement warehouse shall be classified as risk level 1 for the purposes of permit fee assessment under Section 3 of this administrative regulation.

Section 3. Fees.

(1) A permit fee shall be required for inspections conducted by the cabinet or the local health department to determine compliance with:

(a) [902 KAR 45:080 for a salvage distributor or a salvage processing plant;] [(b)] KRS 217.025, 217.035, [and] 217.037, and 217.045 for a food processing plant, [or] food storage warehouse, dietary supplement manufacturer, or dietary supplement warehouse; or

(b) [(c)] KRS 217.085 and 217.095 for a cosmetic manufacturer.

(2) The fee for the inspection of a food, dietary supplement, or cosmetic manufacturing, packaging, storage, or distribution business[processing plant, storage warehouse, or salvage processing facility] shall be:

(a) Assessed according to the:

1. Total square footage of the plant[facility]; and
2. Highest risk level of commodity manufactured by or stored at the plant;[facility.] and

(b) Calculated as established in this paragraph.

1. If the facility is between zero to 1,000 square feet, the fee:
   a. For risk level 1 shall be $135;
   b. For risk level 2 shall be $130; or
   c. For risk level 3 shall be $125.
2. If the facility is between 1,001 to 5,000 square feet, the fee:
   a. For risk level 1 shall be $240[190];
   b. For risk level 2 shall be $225[180]; or
   c. For risk level 3 shall be $215[170].
3. If the facility is between 5,001 to 20,000 square feet, the fee:
   a. For risk level 1 shall be $440[350];
   b. For risk level 2 shall be $375[300]; or
   c. For risk level 3 shall be $315[250].
4. If the facility is between 20,001 to 40,000 square feet, the fee:
   a. For risk level 1 shall be $625[500];
   b. For risk level 2 shall be $565[450]; or
   c. For risk level 3 shall be $500[400].
5. If the facility is between 40,001 to 80,000 square feet, the fee:
   a. For risk level 1 shall be $750[600];
   b. For risk level 2 shall be $690[550]; or
   c. For risk level 3 shall be $625[500].
6. If the facility is between 80,001 to 150,000 square feet, the fee:
   a. For risk level 1 shall be $940[750];
   b. For risk level 2 shall be $910[700]; or
   c. For risk level 3 shall be $845[650].
7. If the facility is greater than 150,000 square feet, the fee:
   a. For risk level 1 shall be $1,300[1,000];
   b. For risk level 2 shall be $1,170[900]; or
   c. For risk level 3 shall be $1,040[800.].

(3) A fee for the inspection of a cosmetic manufacturer shall be $160[$125].

(4) A request for a certificate of free sale or export authorizing a Kentucky [food]processing plant holding a valid permit to operate to export a product outside of the

United States shall be accompanied by a service fee of sixty-five (65)~~[fifty (50)]~~ dollars for each certificate requested.

(5) The annual permit application required by 902 KAR 45:160 and the annual fee required by this section of this administrative regulation shall be due by December 31 each year.

(a) If the annual permit application and annual fee are not received by December 31, a late fee equal to twenty-five (25) percent of the applicable permit fee shall be assessed and added to the total amount due.

(b) If the annual permit application and annual fee are not received by January 31 the following year, a late fee equal to fifty (50) percent of the applicable permit fee shall be assessed and added to the total amount due.

(6) The late payment fees assessed according to paragraph (b) of subsection (5) of this section shall supersede those assessed according to paragraph (a) of subsection (5) of this section. These penalties shall not be assessed cumulatively.

(7) All fees assessed according to this administrative regulation shall be nonrefundable and shall not be prorated.

(8) Fees shall be made payable to the Kentucky State Treasurer and forwarded to the Kentucky Department for Public Health, Food Safety Branch, 275 East Main Street, Frankfort, Kentucky 40621.

902 KAR 45:180
JOHN R. LANGEFELD, MD, Commissioner
STEVEN J. STACK, MD, MBA. Secretary

APPROVED BY AGENCY: October 30, 2026

FILED WITH LRC: November 5, 2026 at 1:40 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on January 25, 2027, at 9:00 a.m. Eastern Time, 8:00 a.m. Central Time, 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 January 15, 2027, 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 through January 31, 2027. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Julie Brooks ,Krista Quarles, Phone Number: (502) 564-7476, (502) 229-3377, Email: CHFSregs@ky.gov, julied.brooks@ky.gov

Subject Headings:Fees, Food and Food Safety, Inspections, Public Health

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the fee structure for food, cosmetic, and dietary supplement manufacturing and processing plants, storage warehouses, and certificate of free sale.

(b) The necessity of this administrative regulation:

The fees collected pursuant to this administrative regulation are necessary to help offset the costs to implement the food, cosmetic, and dietary supplements permitting and inspection activities.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 217.125(2) authorizes the secretary to promulgate administrative regulations to establish the permitting requirements and fee schedule for food processing establishments and food storage warehouses. KRS 211.180(2)(b) requires that fees cover the costs of inspections of manufacturers, retailers, and distributors of consumer products as defined by the Federal Consumer Product Safety Act.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation ensures all food, cosmetic, and dietary supplement manufacturing, processing plants, and storage facilities are properly permitted.

(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 revises the definition for specialized processes, adds a definition for time and temperature-controlled foods, adds dietary supplement manufacturers and storage warehouses to the fee schedule, increases the permit and inspection fee amounts for all but the smallest manufacturing facilities, and adds penalties for late permit renewals.

(b) The necessity of the amendment to this administrative regulation:

The amendment to this administrative regulation is necessary to include dietary supplements as the Department for Public Health's Food Manufacturing Branch has entered into a contract with the federal Food and Drug Administration to begin permitting and inspecting these manufacturing facilities.

(c) How the amendment conforms to the content of the authorizing statutes:

The amendment to this administrative regulation ensures all food, cosmetic, and dietary supplement products manufactured and processed in Kentucky comply with the federal Consumer Product Safety Act in accordance with KRS 211.180. The increase in fee structure conforms to the requirements under KRS 211.180(2)(a)2. KRS 217.992 establishes the penalties for those who violate the provisions of KRS 217.005 to 217.215.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment to this administrative regulation ensures all food, cosmetic, and dietary supplement manufacturing, processing plants, and storage facilities are properly permitted.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

The amendment to this administrative regulation will impact 1,044 food, 120 cosmetic, and sixty (60) to eighty (80) dietary supplement manufacturers. This includes all processing, warehousing, packaging, and storage facilities.

(5) Provide an analysis of how the entities identified in question (4) 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 question (4) will have to take to comply with this administrative regulation or amendment:

All regulated entities will need to be aware of the changes in fee structure and the penalties for not renewing their permit on a timely basis.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

All facilities above 1,001 square feet will pay an increased permit and inspection fee of twenty-five (25) percent.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

All food, cosmetic, and dietary supplement manufacturers and processing facilities will be properly permitted and inspected, and can ensure their products are safe for human consumption and use.

(6) 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 to implement the amendment to this administrative regulation.

(b) On a continuing basis:

The total yearly operating cost for the Department for Public Health's Food Manufacturing Branch is approximately $2.2 million.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:

The Department for Public Health's Food Manufacturing Branch is funded through a mix of revenue received from permit and inspection fees and state General Fund dollars.

(8) 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 is necessary to implement the amendment to this administrative regulation.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

Yes, this administrative regulation establishes the fee structure for permitting and inspecting food, cosmetic, and dietary supplement manufacturing and processing facilities, as well as the fee for the certificate of free sale.

(10) TIERING: Is tiering applied?

Tiering is applied. The permit and inspection fee structure for the smallest manufacturing facilities is not being increased. All other manufacturing facilities will pay a higher permit and inspection fee.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 211.180(2)(b) and 217.125.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Cabinet for Health and Family Services, Department for Public Health, Division of Public Health Protection and Safety, Food Manufacturing Branch, is the promulgating agency.

(a) Estimate the following for the first year:

Expenditures:The current expenditures for the Department for Public Health's Food Manufacturing Branch are approximately $2.2 million annually. These expenditures include staff salaries, program operating costs, and specialized contracts.

Revenues:The Department for Public Health's Food Manufacturing Branch receives $295,755 in revenue from the current permit and inspection fee structure. The proposed increase in permit and inspection fees will result in an increase of approximately $73,938 per year.

Cost Savings:There are no cost savings.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There are no anticipated changes in expenditures, revenues, or cost savings in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

There are no affected local entities.

(a) Estimate the following for the first year:

Expenditures:Not applicable.

Revenues:Not applicable.

Cost Savings:Not applicable.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Not applicable.

(4) Identify additional regulated entities not listed in questions (2) or (3):

Additional regulated entities include 1,044 food, 120 cosmetic, and sixty (60) to eighty (80) dietary supplement manufacturers. This includes all processing, warehousing, packaging, and storage facilities.

(a) Estimate the following for the first year:

Expenditures:The permit and inspection fee for all but the smallest permit holders will increase by twenty-five (25) percent in the first year.

Revenues:This administrative regulation will have no impact on revenues for the additional regulated entities.

Cost Savings:This administrative regulation will not result in cost savings for the additional regulated entities.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There will be no change in expenditures, revenues, and cost savings in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

The amendment to this administrative regulation will generate approximately $73,938 per year in increased revenue for the department.

(b) Methodology and resources used to determine the fiscal impact:

The department currently receives $295,755 in revenue from the current fee structure. The amendment to this administrative regulation proposes a twenty-five (25) percent increase to most permit and inspection fees. The smallest manufacturing facilities will not have an increase in permit and inspection fees. The projected increase in revenue was calculated by multiplying the current revenue by twenty-five (25) percent ($295,755 X 25% (0.25) = $73,938).

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)

The amendment to this administrative regulation will not have an overall negative or adverse major economic impact.

(b) The methodology and resources used to reach this conclusion:

The proposed fee increase will not result in any regulated entity incurring expenses greater than $500,000.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.
21 C.F.R. Parts 111, 113, 114, 121, and 123.

(2) State compliance standards.
The Department for Public Health is directed by the federal Food and Drug Administrative (FDA) on which code of federal regulation to adopt to be in full compliance with the FDA manufacturing standards.

(3) Minimum or uniform standards contained in the federal mandate.
KRS 217.125 authorizes the secretary to promulgate administrative regulations consistent with those promulgated under the federal act. All permits to operate a food processing establishment, food storage warehouse, salvage distributor, or salvage processing plant, are to be renewed annually upon an application submitted with the required fee, and if the establishment is in compliance with KRS 217.005 to 217.215 and the regulations of the cabinet.

(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.
Not applicable.