

Commercial Food and Cosmetic Manufacturing in Kentucky:

A Starter Guide



Kentucky Public Health

Prevent. Promote. Protect.

275 E Main Street, HS1C-F
Frankfort, KY 40621



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*This guide provides the steps, resources, guidance, and contact information you will need to become a **Cosmetics Manufacturer** or **Food Manufacturer**.*

Food Manufacturers include food processing, storage, or distribution operations, and typically engage in wholesaling (products not sold directly to the consumer). Other special considerations can result in classification as a Food Manufacturer.

Retail Food operations (product sold directly to the consumer) engaged in less than 25% wholesale should visit [The Kentucky Food Safety Branch's Retail Food webpage](#) for guidance.

Use the links below to learn more about how to become a permitted manufacturer:

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Step-By-Step Checklist

Wondering where to start with a new food or cosmetic manufacturing business in Kentucky? This guide will walk you through the entire process step-by-step, and provide the resources you'll need to understand rules, regulations, procedures, and other requirements.

Use the checklist below to work your way through this guide, and achieve every step on the way to opening your business:

- 1 Learn about the rules and regulations governing manufactured food.**
Know where to access these rules for your reference and understand what federal registrations might apply to your business. See pages 4-6.
- 2 Know how to prevent foodborne illness and ensure food safety.**
Understand requirements for training plans, food safety plans, and food security. See pages 7-8.
- 3 Determine what products you will manufacture.**
Will you manufacture cosmetics, food, or both? Many foods have special requirements. For food, see pages 9-17. For cosmetics, see page 18.
- 4 Review permitting requirements.**
Know what permits and fees will be required for your products. See page 19.
- 5 Locate a commercial-grade facility for your business.**
Review building and water requirements and find a location that meets these standards. See pages 20-21.
- 6 Contact your area inspector to set up an opening inspection.**
View the map to find your inspector on page 24.
- 7 Create product labels.**
Understand label requirements and create a label to submit for review prior to your opening inspection. See pages 22-23.
- 8 Demonstrate your process at your opening inspection.**
Inspectors observe this process and inspect your facility, then complete application paperwork and submit it to the Food Safety Branch in Frankfort for final review.
- 9 Pay for and receive your permit.**
Either at your inspection or once you receive an invoice, pay by check or money order made payable to the "Kentucky State Treasurer." Once your fee is paid and your application has been approved at the Frankfort office, your permit to operate will be mailed to you. Congratulations!



Rules & Regulations

Food and cosmetic manufacturing firms are regulated under federal Food and Drug Administration (FDA) regulations, as well as state laws and regulations.

Use the information and links below to familiarize yourself with the rules that will govern your new business:

Federal Regulation

Current good food manufacturing practices, referred to as **GMPs**, are published in the Title 21 of the Code of Federal Regulations, Part 117. GMPs describe the methods, equipment, facilities, and controls for producing processed food. As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety for the nation's food supply. GMPs also serve as the basis for manufactured food inspections.

The Food and Drug Administration's (FDA) **Food Safety Modernization Act (FSMA)** is federal legislation signed into law on January 4, 2011. Considered to be the most sweeping reform of our national food safety laws in more than 70 years, FSMA aims to ensure the safety of the U.S. food supply by emphasizing prevention. After nearly four years of rulemaking at the federal level, several new rules related to FSMA were published in the Code of Federal Regulations. Given the scope of the FSMA rules, including the "Preventive Controls for Human Food," Kentucky food plants are encouraged to visit FDA's website for more information on how the rules may affect their operation.

Resources

A great place to review these and other federal requirements for new food businesses is the FDA website. The FDA site contains links to applicable federal food laws and regulations, food labeling information, and other useful resources for the food industry:

[How to Start a Food Business | FDA](#)

[Food Industry Resources | FDA](#)

[Current Good Manufacturing Practices \(CGMPs\) | FDA](#)

[Food Safety Modernization Act \(FSMA\) | FDA](#)

State Law & Regulation

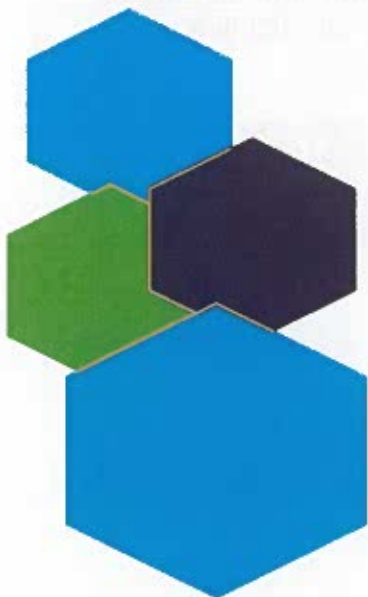
Manufacturers in Kentucky are regulated under the authority of the [Kentucky Food, Drug & Cosmetic Act \(KRS 217.002 to 217.998\)](#), a law designed to protect consumers from the sale of adulterated, misbranded and mislabeled products.

Did you know?

The [Kentucky Food Safety Branch website](#) contains more helpful information about state regulations and houses many resources to assist you in your manufacturing journey.

The [Kentucky Food and Cosmetic Processing, Packaging, Storage, and Distribution Operations Regulation \(902 KAR 45:160\)](#) is an administrative regulation that establishes procedures and requirements for food and cosmetic processing, packaging, storage, and distribution operations in Kentucky. In addition to formally adopting longstanding Kentucky requirements which mirrored specific federal (Food and Drug Administration) Code of Federal Regulations requirements for food and cosmetic firms, the regulation also contains food and cosmetic plant requirements regarding permit issuance, plan review, construction and maintenance, water supply, plumbing, sewage disposal, toilet facilities, hand washing facilities, and food transportation.

The regulation also establishes a food and cosmetic plant **inspectional frequency** which is based on the degree of risk associated with the food commodity or cosmetic processed, packaged, stored, or distributed by a plant. In addition, a classification system for violations/objectionable conditions, environmental and food product sampling provisions, notification requirements for imminent health hazards, and formal enforcement provisions are established by this regulation.



Resources

Use the below links to get to know Kentucky's rules and regulations for food and cosmetics:

[Kentucky Food, Drug & Cosmetic Act](#)

[Kentucky Food and Cosmetic Regulation](#)

[Kentucky Food Safety Branch Website](#)

Registration & Attestation

Depending on what you manufacture and the size of your business, the FDA requires that you complete certain registrations and attestations, and maintain certain records.

Use the information and links below to familiarize yourself with these requirements and learn how to complete them:

FDA Food Facility Registration

Certain facilities that manufacture, process, pack or hold food for human or animal consumption in the United States are required to register with FDA. This website contains all the information you need to understand and meet the requirements: [Registration of Food Facilities and Other Submissions | FDA](#)

As part of the [federal Bioterrorism \(BT\) Act](#), regulations may require you to maintain records that can be used to identify the immediate supplier to and recipients of food that you manufacture.

FDA Qualified Facility Attestation

Small business that meet the definition of a ["qualified facility"](#) are subject to modified requirements of the [preventive controls rules](#). For information on how to determine whether your facility meets the definition of "qualified facility," see FDA's guidance document: [Determining Your Status as a Qualified Facility | FDA](#)

Qualified facilities must submit attestation to the FDA, [either in hard copy or online](#). This includes attesting to your business' status as a qualified facility, and that your facility implements preventive controls to address hazards associated with its food or complies with non-Federal food safety laws and regulations. Note that facilities must first have a valid food facility registration to submit this attestation.

Resources

Use the below links to find resources on registration and attestation:

[Registration of Food Facilities and Other Submissions | FDA](#)

[Determining Your Status as a Qualified Facility | FDA](#)

[Attest Online via the Qualified Facility Attestation \(QFA\) Module | FDA](#)

[How to Attest with Hard-Copy Forms | FDA](#)

Foodborne Illness & Food Safety

Manufacturing food is serious business -- the potential for making a good profit cannot overshadow the risks that comes with providing food to thousands of people. By learning about and taking responsibility for food safety, staff training, and security, you can prevent foodborne illnesses.

Food Safety Plans

The [preventive controls for human food rule](#) establishes a requirement for facilities to have **written food safety plans (FSPs)**. However, small businesses that meet the definition of a "[qualified facility](#)" are exempt from this requirement.

If no exemptions apply to you, then you are required to have a **Preventive Controls Qualified Individual (PCQI)** develop and implement your facility's written FSP. A person can qualify as a PCQI either through job experience, or by taking the [FSPCA Preventive Controls for Human Food Training](#). When written FSPs are required, they should include:

- Hazard analysis to identify whether there are hazards requiring a preventive control. Where this analysis identifies a hazard requiring a preventive control, the FSP should also include the following written documents as appropriate: process controls, food allergen controls, sanitation controls, supply-chain controls, and a recall plan
- Procedures for monitoring implementation of preventive controls
- Corrective action procedures
- Verification procedures
- Validation of process controls

For more information on building a food safety plan, the FDA has many resources. The following link provides a tool for owners and operators of food facilities to develop a comprehensive food safety plan specific to their facility: [Food Safety Plan Builder | FDA](#)

Training

Training is required for all employees working in the food and cosmetic manufacturing industry regardless of firm size. The following applies to all stages, from processing to packaging:

- Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
- Employees must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility and the individual's assigned duties.
- Records documenting training for each employee **must be kept**.

Reportable Food Registry

Facilities that manufacture, process, pack, or hold food for human or animal consumption are required to report when there is a reasonable probability that food will cause serious adverse health consequences or death to humans or animals.

The Reportable Food Registry (RFR or the Registry) is an electronic database used by food manufacturers to report the reasonable probability that food will cause serious health problems. The Registry helps the FDA better protect the public by tracking patterns and targeting inspections. The RFR applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula.

Did you know?

The **US Centers for Disease Control (CDC)** estimates that about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from food-borne diseases!

Food Security

Protecting the food supply from intentional, as well as unintentional, contamination involves not only regulatory officials, but food industry stakeholders as well. Self-inspections and self-audits are one tool the food industry can use to ensure food safety and food defense issues are being addressed. **Several documents** are available to help you form a good security plan.

You may find this online training course helpful: **[An Introduction to Food Security Awareness](#)**.

Resources

Use the below links to find resources on food safety and security:

[Food Safety Plan Builder | FDA](#)

[The Reportable Food Registry \(RFR or the Registry\)](#)

[Training: An Introduction to Food Security Awareness](#)

[Guidance for Industry: Food Security Preventive Measures](#)



Food Operations with Special Requirements

Some manufacturing operations have special requirements. This information is not meant to cover every type of manufacturing operation, but provides guidance for the most common.

The science of food processing can be highly complicated. By utilizing a **Hurdle Approach** and monitoring a few basic factors in food safety, most foods can be kept safe. The **Hurdle Approach** is the combination of multiple preservation methods, including physical, chemical, and biological factors as a preservation strategy. The most important hurdles commonly used in food preservation are based on controlling temperature, water activity, acidity, and modified atmosphere.

Let's look at some foods whose safety and quality especially depend on these things.

Low-Acid Foods and Acidified Foods

Acidity (or low pH) is a very effective way to keep harmful bacteria from growing. The most common form of acidifying a food is by pickling. Scientifically speaking, **acidifying** is the use of an acid (commonly vinegar- acetic acid) to reduce the pH of a product to below 4.6. This is the acidity level that most bacteria won't survive at in foods.

It is important to realize that most vegetables and even some fruits (like tomatoes and cucumbers) have a pH well above 4.6. This makes them prone to harboring certain kinds of bacteria that can make people sick, or even kill them!

Clostridium Botulinum is the pathogen of most concern. *C. botulinum* is the cause of botulism, a disease caused by neurotoxins formed by the bacteria. Botulism is fatal in 60% of cases if not treated. But even with treatment, it often causes life-long disabilities. You may have heard that botulism often comes from canned foods. But how can any bacteria grow in canned food?

C. botulinum is an anaerobic bacteria. This means it only grows when there is little or no oxygen. Canned food can be the perfect environment for growing *C. botulinum* unless a few preventative measures are taken. This takes us back to the pH level. *C. botulinum* is not viable in food that has an acidity of 4.6 or less. That is what makes acidifying—when done correctly—such an effective way of preserving food.

But what about canning vegetables that aren't acidified? How can we keep them safe from bacteria like *C.botulinum*?

Canned foods with a final pH of more than 4.6 are called **Low-Acid Canned Foods, or LACFs**. LACFs require special processing procedures to reduce the risk of botulism. This includes all canned vegetables and other food items such as pepper (or other herb & vegetable) jellies.

Because botulism is such a serious illness, the Food Safety Branch requires anyone who acidifies or cans low-acid or acidified products to complete two steps, in addition to normal permitting requirements:



1

Successfully complete an approved **Better Process Control School (BPCS)**. Below under *Resources*, we have provided a list of some organizations that provide BPCS training.

2

Review and approval of all recipes by a **Process Authority (PA)**. A Process Authority is a food scientist who determines whether your recipe and finished product is defined as an “acidified” or “low-acid” food according to federal regulations. The Process Authority will review your written recipe and test a sample of your finished product as part of the evaluation.

3

Complete **FDA Registration and Process Filing**. Manufacturers producing Acidified Foods or Low-Acid Canned Foods must register and file their processes with the FDA. This process can be completed either online or using hard-copy forms.

Resources

Better Process Control Schools

[UK's Food Systems Innovation Center](#)

[Grocery Manufacturers Association](#)

[University of California at Davis' Online BCPS](#)

[University of Tennessee Extension](#)

[Purdue University](#)

Process Authority Search

The Association of Food and Drug Officials (AFDO) maintains a state Process Authority search engine. Authorities are listed in no particular order, and the presence or absence of a facility does not represent or constitute an endorsement or rejection, any of its sub-offices, or individual employees. To get started, please visit <https://www.afdo.org/directories/fpa>

FDA Registration & Process Filing

[Registration & Process Filing for Acidified and LACFs | FDA](#)

Juice & Cider

Depending on the details of a specific operation, most juice and cider manufacturers are subject to FDA's Juice HACCP regulation. Like the requirements for Seafood, each juice processor would be required to conduct a Hazard Analysis of the operation and construct a HACCP Plan if Critical Control Points were found. Also, the person responsible for conducting the Analysis or writing the HACCP Plan must be properly trained on HACCP principles.

FDA has compiled all the information a juice processor might need on one convenient website. Any firm that wants to make juice or cider should review the following resources carefully:

[Juice HACCP Resources | FDA](#)

Bottled Water

1

First, the source of the water must be approved by the [Kentucky Division of Water](#). This is the office responsible for city water systems and any and all drinking water provided to the public. See below for contact information, links to Drinking Water Regulations, and other helpful information for potential bottlers:

[Drinking Water Resources | DOW](#)

[Bottled Water Fact Sheet | DOW](#)

[Kentucky Administrative Regulation 401, Chapter 8 - Public Water Supply](#)

2

Once your source water has been approved, the [Food Safety Branch](#) will conduct an opening inspection of your facility, review your product labels, and complete the paperwork necessary to permit you as a food manufacturer.

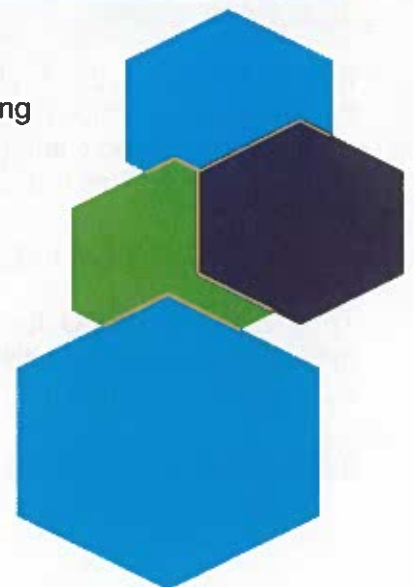
You should know that all bottled water manufacturers in Kentucky shall comply with the federal requirements pertaining to bottled water; including source water sampling, finished product sampling, product standard of identity requirements, operator certification requirements, and record keeping/record retention requirements.

View FDA guidance at:

[Bottled Water: Small Entity Compliance Guide | FDA](#)

View federal regulation at:

[21 CFR 129 Processing and Bottling of Bottled Drinking Water](#)

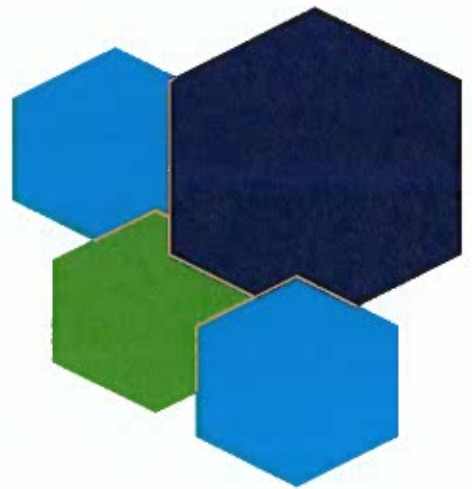


Produce

Contact the [Food Safety Branch](#) to understand what permits your produce operation might require. All produce growers, shippers, and retailers are expected to use **Good Agricultural Practice (GAP)** principles to ensure a safe, nutritious product.

The [Kentucky Department of Agriculture](#) has some excellent reference documents on GAP for specific commodities. You can find that information here:

[GAP Resources | KDA](#)



Seafood & Shellfish

As an inland state, many people do not realize that Kentucky has a substantial seafood industry. Farm-raised catfish, tilapia and prawn, and wild-caught paddlefish & paddlefish roe are just a few of the seafood products that the Commonwealth offers.

[The Department for Fish and Wildlife Resources](#) regulates commercial fishing in Kentucky. They are responsible for deciding which waters are “open” to commercial fishing. For more information pertaining to commercial fishing licenses and a listing of “open” waters, call 1-800-858-1549 or visit online at:

[Commercial Licenses | DFW](#)

Those who want to process any wild-caught or farm-raised fish should contact the [Kentucky Food Safety Branch](#) regarding state and federal permit/inspection requirements.

Catfish

Effective March 1, 2016, all establishments that slaughter and process fish and fish products of the Order Siluriformes (catfish) for human food will be subject to USDA inspection under the agency’s “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish” rule. This rule can be found at:

[Mandatory Inspection of Fish of the Order Siluriformes | FSIS](#)

The USDA-FSIS-OFO Jackson, Mississippi District Office processes Federal Grants of Inspection for Siluriform fish processors. Please contact the Jackson, MS District Office at (601) 965- 4312 or visit online at:

[Inspection of Siluriformes | FSIS](#)

Seafood Hazard Analysis Critical Control Points (HACCP)

Processors of *fish other than catfish* remain under FDA/State inspection and are required to follow established **Seafood HACCP** requirements.

The National Seafood HACCP Alliance was formed to help regulators and seafood producers understand and use HACCP principles. The Alliance hosts the first segment of training on its website at:

[Seafood HACCP Online Training Course | Cornell](#)

The second segment of the course is a classroom exercise held in many places across the country. View more information about the practical training segment and view current scheduling at:

[Segment Two – Instructor Training | Cornell](#)

Shellfish (Oysters, Mussels, & Clams)

Food plants in Kentucky who receive and reship shellfish (oysters, mussels, and clams) are subject to Kentucky's Shellfish Dealer Standards and Requirements regulation (902 KAR 45:020). The regulation can be accessed at:

[902 KAR 45:020. Kentucky shellfish dealer standards and requirements](#)

The Interstate Certified Shellfish Shippers List (ICSSL) is a monthly publication that lists shellfish dealers that meet the requirements of the National Shellfish Program (NSP). Listed Dealers are then permitted to ship product in interstate commerce. The most up-to-date list is here:

[Interstate Certified Shellfish Shippers List | FDA](#)

Meat Products & Eggs

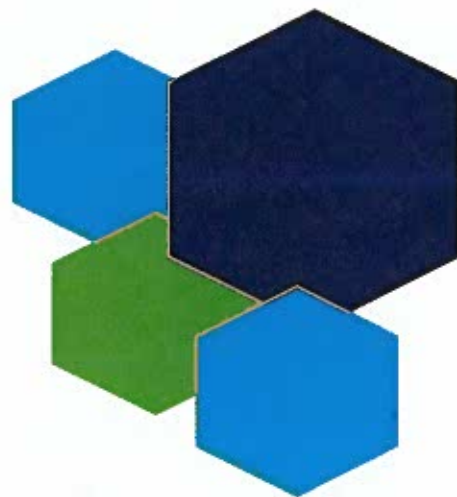
As a rule, the [United States Department of Agriculture \(USDA\)](#) has jurisdiction over the commercial manufacture or processing of food products containing meat and/or poultry and eggs. This means that all meats and food products containing meat must bear the USDA Mark of Inspection.

There are a few ways to obtain this Mark of Inspection. First, you can simply have all of your meat processed by a slaughterhouse that staffs a USDA Inspector. Alternatively, your own production facility could staff an Inspector (and in certain circumstances will be required to).

Some meat production plants will require permits from both the USDA and the Kentucky Food Safety Branch because the USDA regulates only a very specific set of food products. If your manufacturing firm produces meat products and other items not containing any meat, you will be open to inspection and permitting by both agencies.

If you plan to process and sell home-grown meat or make a product that contains meat, your first contact should be the **Jackson, Mississippi Branch** (district 90) of the USDA's Office of Field Operations (OFO). You can find up-to-date contact information for the Jackson Field Office at:

[OFO Contact Us | USDA](#)



Poultry

Some small-scale poultry producers are exempted from USDA regulation and the [Federal Poultry Products Inspection Act](#). If your operation falls outside of USDA jurisdiction, we require you to obtain from USDA a "letter of release" from USDA jurisdiction. Exempted products must bear the statement: "Exempt P.L. 90- 492."

[OFO Contact Us | USDA](#)

Being exempted from USDA jurisdiction, however, does not exempt a processor from [Kentucky's Food, Drug, and Cosmetic Act](#). It is the responsibility of the Kentucky Food Safety Branch to ensure that all food is produced, processed, and marketed under safe, wholesome conditions. This means that USDA-exempt poultry processors must obtain a manufacturing permit from the Food Safety Branch.

In general, the plumbing and kitchen requirements for a small-scale poultry producer will be the same as any other manufacturer. However, some special rules apply as follows.

The facility shall be designed such that there is ample protection between the slaughter and processing areas, to prevent cross contamination from the slaughter operation. At a minimum, a wall between the two unit operations is required.

In addition, USDA-exempt poultry processing establishments are required to conduct a Hazard Analysis, formulate a written Hazard Analysis Critical Control Point (HACCP) plan based upon the Hazard Analysis, and draft a written Sanitation Standard of Operation Procedure (SSOP) that details how food will be handled safely and the facility will be cleaned. These documents are required before a permit can be issued.

Rabbits & Other Non-Amenable Species

Some meats and meat products are *not* regulated by the USDA, regardless of the scale of operation. These animals are referred to as “non-amenable species.” Non-amenable species would include things like most fish, bison, quail, elk, deer, and big game animals. Rabbits also fit into this category.

Processors must also conduct a Hazard Analysis, formulate a written Hazard Analysis Critical Control Point (HACCP) plan based upon the Hazard Analysis, and draft a written Sanitation Standard of Operation Procedure (SSOP) that details how food will be handled safely and the facility will be cleaned.

Several of Kentucky’s universities are able to assist exempt and non-amenable species processors. Additionally, USDA provides the following help to small processors:

[Small and Very Small Plant Outreach | USDA](#)

Eggs

Farmers may sell up to 60 dozen eggs per week, directly to consumers, without a license. Eggs shall be kept refrigerated at a temperature of 45° F during transport and storage.

Permitting for egg production and sales beyond that limit is NOT regulated by the Food Safety Branch. Instead, you must obtain a license from the [Kentucky Department of Agriculture](#). Note that there are two types of Egg Licenses: retail (for direct-to-consumer sales) and wholesale (for sales to groceries, restaurants, etc.) To get either of these permits, contact the Kentucky Department of Agriculture’s Egg Marketing Program:

[Egg Marketing and Licensing | KDA](#)

Syrup, Sorghum, & Honey

Sorghum & Maple Syrup

Maple syrup and sorghum have been added to the list of allowable items for home-based processors.

Maple syrup and sorghum producers who meet all requirements for [home-based processing](#) should [register](#) as home-based processors and sell directly from the home/farm, by direct-to-consumer delivery, at a farmer’s market, or at a community event. They should not surpass \$60,000 per year in gross sales.

Maple syrup producers and sorghum producers who are making more than \$60,000 in gross sales per year **OR** who wish to sell to retailers/via wholesale/via mail/ across state lines should be permitted as Food Manufacturers and work with [their area inspector](#).

Honey

Per [KRS 217.187](#), if a person sells **less than** 150 gallons of honey in a year off the farm, the person shall not be required to process the honey in a certified honey house or food processing establishment, nor shall the person be required to obtain a permit from the cabinet.

Apiaries meeting this exemption will still need to comply with Kentucky's labeling requirements and operate in a safe and sanitary manner. Product labels should be submitted to the Kentucky Food Safety Branch at food.safety@ky.gov for review. The subject line should read: **Attention: Labels**



Honey Labeling

Labels for honey containers, as for all foods in Kentucky, are regulated by the Kentucky Food Safety Branch. However, the required labeling for 100% honey differs some from other foods. The requirements for honey labels are detailed below.

1 Identity of the product: HONEY

Net Quantity: honey is customarily stated in weight - ounces and grams, not volume:

- 2
- A *one-pound* jar label should state Net Wt. 1 lb (454 g).
 - A *two-pound* jar should state Net Wt. 2 lb (908 g).
 - A *one-pint* jar should state Net Wt. 22 ounces (624 g) or Net Wt. 1.37 lb (624g).
 - A *one-quart* jar should state Net Wt. 44 ounces (1.2 kg) or Net Wt. 2.75 lb (1.2kg).

- 3
- Name of manufacturer:** This is your name or your company's name. If you are bottling honey purchased from another producer, the words "Bottled by", "Distributed by", or "Manufactured for" are also required in addition to the name.

- 4
- Address of Manufacturer:** Your complete address including the street address, city, state, and zip code are required.

For the most current FDA draft guidance on the labeling of all honey products, visit:

[Guidance for Industry: Proper Labeling of Honey and Honey Products | FDA](#)

Ice Cream & Dairy

The permitting requirements for "ice cream" depend on your specific recipe. Normally, "ice cream" made from a pre-pasteurized mix is permitted by the [Kentucky Food Safety Branch](#). However, if you intend to manufacture ice cream from 'scratch,' you'll need to contact the [Kentucky Milk Safety Branch](#).

In fact, all other dairy products—including cheese, yogurt, sour cream, etc.—are regulated and permitted by the [Milk Safety Branch](#). If you have a product that falls into this category, call 502-564-3340 for more information.

Products Containing Alcohol

Confections & Candies

According to [KRS 244.650](#), confections or candies containing more than one-half percent (0.5%) but not more than five percent (5%) of alcohol by volume or weight may be sold.

Manufacturers producing confections and candies containing alcohol must be able to provide documentation of the product's residual alcohol level.

If the product does contain between one-half percent (0.5%) but *not more* than five percent (5%) of alcohol by volume or weight, the product label must contain the statement:
"SALE OF THIS PRODUCT TO PERSONS UNDER 21 YEARS OF AGE IS UNLAWFUL."

Other Products

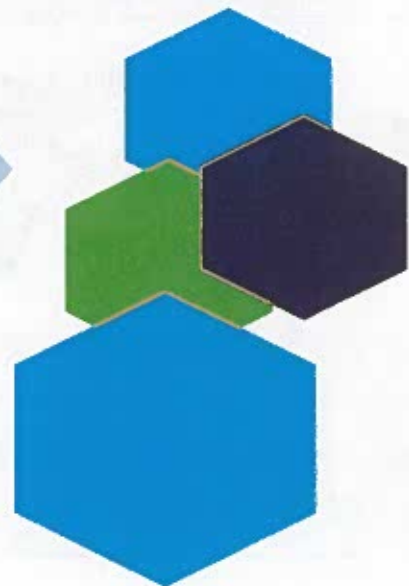
Other products containing alcohol may require a permit from the [Kentucky Department of Alcoholic Beverage Control](#). For more information, please contact them at (502) 564-4850 or view contact information here:

[Contacts | KYABC](#)

Pet Treats & Food

Pet treats—and all other pet foods—are regulated by the [University of Kentucky's Division of Regulatory Services](#). You may contact them at (859) 257-2785 or view their guidance on pet treat production at:

[Kentucky Pet Treat Packet | UK](#)



Cosmetics

Cosmetics manufacturing operations are permitted and inspected through the Kentucky Food Safety Branch. All cosmetics manufacturers are subject to the same fixture/structural and permit requirements as food plants.

[Kentucky's Food, Drug & Cosmetic Act](#) defines the term "cosmetic" as:

Articles intended to be rubbed, poured, sprinkled, or 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

Articles intended for use as a component of any such articles, except that such term shall not include soap.

Definition of "Soap"

So, what's the regulatory definition of "soap"? Whether a product is a "soap" in the traditional sense, or is really a synthetic detergent, helps determine how the product is regulated. To meet the definition of soap in FDA's regulations, a product must meet three conditions:

1

What it's made of: to be considered "soap," the product must be composed mainly of the "alkali salts of fatty acids," that is, the material you get when you combine fats or oils with an alkali, such as lye.

2

What ingredients cause its cleaning action: to be considered "soap," those "alkali salts of fatty acids" must be the only material that results in the product's cleaning action. If the product contains synthetic detergents, it's a cosmetic, not a soap. You still can use the word "soap" on the label.

3

How it's intended to be used: to be considered "soap," it must be labeled and marketed only for use as soap. If it is intended for purposes such as moisturizing the skin, making the user smell nice, or deodorizing the user's body, it's a cosmetic. Or, if the product is intended to treat or prevent disease, such as by killing germs, or treating skin conditions, such as acne or eczema, it's a drug. You can still use the word "soap" on the label.

Resources

[Federal Regulation on Soap, 21 CFR 701.20](#)

[Is It a Cosmetic, a Drug, or Both? \(Or Is It Soap?\) | FDA](#)

[Kentucky Cosmetic Regulation](#)

[Cosmetic Guidance | FDA](#)

Permitting

[Kentucky's Food, Drug, and Cosmetic Act](#) stipulates that "No person shall operate a... processing establishment without having obtained an annual permit to operate from the Cabinet." All permits (both food and cosmetics) are based on the calendar year and expire on December 31 annually. Permits are not pro-rated.

Risk Levels & Fees

Food permit type is usually determined by whether your operation is primarily wholesale or retail in nature. Food manufacturing operations that wholesale their product (sales to another wholesale or retail outlet) are permitted and inspected through the [Kentucky Food Safety Branch](#). [Retail](#) operations, selling direct to consumer, are permitted by their [Local Health Department](#). Retail operations may wholesale up to 25% of product sales under their retail permit.

Note that special considerations can result in classification as a Food Manufacturer, such as the scale of the operation or certain high-risk processes. For example, low acid canned foods (high pressure canned food) are permitted by the Kentucky Food Safety Branch for retail and manufacturing operations.

The permit fee schedule for food plants, including food processing, storage, or distribution operations, is based on **square footage and risk level**. Cosmetic manufacturer permits are considered low risk and the rate is \$125 per year. Note that food and cosmetic permits are separate. Firms that manufacture both **food and cosmetics** must hold **both** permits. See the chart below to view fees:

Effective 2/11/2021

| Size (sq ft) | Low Risk | Medium Risk | High Risk |
|----------------|----------|-------------|-----------|
| 0 -1,000 | \$125 | \$130 | \$135 |
| 1,001-5,000 | \$170 | \$180 | \$190 |
| 5,001-20,000 | \$250 | \$300 | \$350 |
| 20,001-40,000 | \$400 | \$450 | \$500 |
| 40,001-80,000 | \$500 | \$550 | \$600 |
| 80,001-150,000 | \$650 | \$700 | \$750 |
| >150,000 | \$800 | \$900 | \$1,000 |
| Cosmetics | \$125 | | |

Kentucky Business One Stop Portal

In addition to permits related to food safety, there may be other permits and registrations needed for your business. The Kentucky Business One Stop Portal provides a single point of contact for Kentucky businesses to register with the Secretary of State and the Revenue Cabinet. (Please note, however, that this website CANNOT be used to obtain a Food Manufacturing Permit.) Access the portal here: [Kentucky One Stop Portal](#)

Building, Fixture & Water Requirements

Your new food operation must meet certain building, fixture, and water supply requirements in order to meet the standards of a commercial-grade facility.

Read below to familiarize yourself with these requirements:

Building & Fixtures

As a rule, every manufacturing facility must meet the following requirements:

- 1 Be constructed of smooth, non-absorbent and easily cleanable materials and be designed to be insect/rodent-proof.
- 2 Be connected to a municipal water source or have a water supply approved by the Kentucky Division of Water (details follow).
- 3 Be connected to a municipal sewer or an approved onsite septic system.
- 4 Feature a hand wash sink in the food preparation area, utensil wash area, and each restroom.
- 5 Include a three-compartment sink with drain-boards for washing utensils.
- 6 Have a utility/mop sink.
- 7 Have restroom facilities approved by the KY Division of Plumbing.

Please note that construction plans for all new or renovated facilities, regardless of retail or wholesale operations, shall be submitted for review through the area's Local Health Department.

You can find your Local Health Department here:

[Local Health Department Listing](#)

Commercial food preparation operations shall not be conducted in a residential kitchen. This does not necessarily mean that commercial food preparation cannot be conducted in a private residence, but it does mean that a separate, dedicated commercial kitchen is required.

If a commercial kitchen is being installed in a private residence, it must be completely separated from the domestic kitchen and living quarters of the home. Any food products to be sold as part of the business must be stored separate and apart from personal items at all times. The plans for such a kitchen must be submitted to the Local Health Department to be approved by the local plumbing inspector before you begin any construction. Also, remember to check with local zoning authorities to be certain your plans allow for commercial construction in your area.

[Division of Plumbing Contact Info | PPC](#)

There are several other options for meeting the requirements for a commercial kitchen. You may wish to use an already-permitted kitchen or a kitchen that would comply with the requirements outlined above. A restaurant kitchen before/after its normal business hours, a church kitchen outfitted with commercial fixtures, and many county extension kitchens are all possibilities.

The [University of Kentucky Cooperative Extension Office](#) and the Food Safety Branch maintain a list of commercial kitchens that are available for rent in Kentucky. You can view that list here:

[Commercial Kitchens in Kentucky](#)

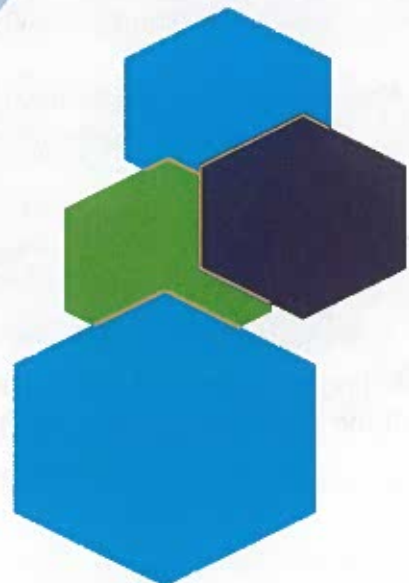
Should you choose to use one of these facilities, the Food Safety Branch will need a copy of a written agreement between you and the permitted establishment, certifying that you have access to the facility and that all your product will be manufactured there during times when the kitchen is not in use.

You may also wish to have your food product manufactured for you by a permitted food processing facility. These contract manufacturers are known as “**co-packers.**” A co-packer prepares food based on your recipe, packages it, and labels it with your custom label. Should you choose to contract with a co-packer, you would not require a permit to operate a food manufacturing plant—although it is possible you could be required to obtain a warehousing permit. Contact the Food Safety Branch to make a determination on your particular situation.

Water Supply

Wells, cisterns, springs, and all other private water supplies must be approved by the Kentucky Division of Water before being permitted as a food processing plant. You may contact the Division of Water by telephone at (502) 564-3410 or online at:

[Division of Water | EEC](#)



Labeling

New food and cosmetics manufacturers should have a product label reviewed by the Kentucky Food Safety Branch prior to being permitted as a manufacturer. Before the opening inspection, new manufacturers should submit a sample label for review directly to the Food Safety Branch via e-mail at: food.safety@ky.gov

Please format labels as PDF attachments, use the subject line "**ATTENTION: LABELING**," and include your county name in your message. The Labeling Compliance Specialist will provide email feedback on your label submission.

For other labeling inquiries, please contact the KY Food Safety Branch at (502) 564-7181 and select the menu option for labeling. Read on below to find out more about requirements for food and cosmetic product labels:

Cosmetics

Cosmetics marketed in the United States, whether manufactured here or imported from abroad, must be in compliance with the provisions of the [Federal Food, Drug, and Cosmetic Act \(FD&C Act\)](#) and [Fair Packaging and Labeling Act \(FP&L Act\)](#).

As a general rule, all cosmetics have the following label requirements:

- 1 Statement of Identity.** What is your product? What is it commonly called? It should be the most prominent printed statement on the label.
- 2 Net Quantity of Contents.** How much product is contained in the package? For liquid products, express this in terms of volume. For non-liquids, use weight.
- 3 Ingredients Statement.** Include each ingredient in decreasing order of predominance. Any sub-ingredients should be listed in parenthesis following the ingredient name.
- 4 Name and Address of the Manufacturer or Distributor.** This includes the street address, city, state, and zip code. If the company name as it appears on the label is listed in a current city directory or telephone directory, then the street address may be left off.

Labeling requirements vary based on your specific cosmetic product. For more information, visit the FDA's [Cosmetic Labeling Guide](#) and [Summary of Cosmetics Labeling Requirements](#).



Foods

The following information is required on all packaged food products in Kentucky:

1

Statement of Identity. What is your product? What is it commonly called? It should be the most prominent printed statement on the label. Be sure to include descriptors such as whole, sliced, or shredded.

2

Net Quantity of Contents. Shall be expressed in English and Metric units. Shall be placed in the lower 30% of the label. Most commonly it is the last printed line on the label. Always round down. 1 oz = 28 g, 1 fl oz = 30 ml, 1 lb = 454 g.

3

Ingredient Statement. Each ingredient shall be listed in the ingredient statement in decreasing order of predominance. Sub-ingredients shall be listed in parenthesis following the ingredient. For example, ketchup would be listed as: Ketchup (tomatoes, vinegar, high fructose corn syrup, and onion powder).

Proteins derived from MILK, EGGS, WHEAT, SOY, PEANUTS, TREE NUTS, SESAME, FISH, & SHELLFISH shall be identified by name within the ingredient statement or in a separate all-inclusive "Contains" statement.

4

Name and Address of the Manufacturer or Distributor. This includes the street address, city, state, and zip code. If the company name as it appears on the label is listed in a current city directory or telephone directory, then the street address may be left off. When products are not manufactured by the name appearing on the label, use a statement such as "Manufactured for" or "Distributed by" to express the relationship.

Formatting

The **statement of identity** and **net quantity of contents statement** are required to be on the principal display panel (main label, front of the package or top of the package). The **ingredient statement** and **name & address of the manufacturer or distributor** may be on separate labels either on the back or bottom of the package.

All print shall be no smaller than 6 pt. font. This is 6pt font.

Nutrition Facts Panels

Many small-scale food manufacturers are exempted from the well-known Nutrition Facts Panel (NFP). The details for this exemption can be found here in the [Small Business Nutrition Labeling Exemption Guide](#). Note that if you use a statement that references a nutrient, like "Low Salt", "No Sugar", "Reduced Calorie", "Low Fat", "Low Cholesterol", or "High Fiber," then a nutrition facts panel is automatically required.

Resources

Food Labeling

[Food Labeling Guide | FDA](#)

[CFR Title 21 Part 101 Food Labeling](#)

[All Labeling & Nutrition Guidance and Regulations](#)

[Small Business NFP Exemption Guide](#)

[Sesame as a Major Allergen | FDA](#)

Cosmetics Labeling

[Cosmetic Labeling Guide | FDA](#)

[Summary of Cosmetics Labeling Requirements | FDA](#)

[Cosmetics Labeling Regulations | FDA](#)

Contact Information

After completing the steps outlined in this guide, you will be ready to contact your Area Food Manufacturing Inspector to schedule an opening inspection.

Kentucky is divided into several inspector districts. View the map below to locate your inspector:

[Food Manufacturing Inspectors Area Map](#)

Questions?

Have questions? Contact the Kentucky Food Safety Branch via phone at (502) 564-7181, or email us at:

food.safety@ky.gov