

Commercial Food Manufacturing in Kentucky: A Starter Guide



Kentucky Public Health

Prevent. Promote. Protect.

275 E Main Street, HS1C-F

Frankfort, KY 40621

<http://chfs.ky.gov/dph/info/phps/food.htm>

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Getting Started: A Quick Checklist

1. Determine what products you will manufacture
2. Review the section of this Guide which covers that product
3. Locate a commercial-grade facility that meets building requirements (pg. 7)
4. Contact your area inspector to set up an opening inspection (see map on pgs. 42- 43)
5. Demonstrate your process and provide a draft label (pg. 10) at your opening inspection
6. Provide a check or money order, made payable to: Kentucky State Treasurer (pg. 6)

After you've met the facility and process requirements, your Area Inspector will complete your application and submit it to the Food Safety Branch for final review. Once your application is approved, your permit to operate will be mailed to you.

Kentucky has a legendary tradition of being home to some of the finest cooking found in the United States. Our rich heritage has proven to be the perfect backdrop for many successful food enterprises. If you have the next great recipe and are eager to get started manufacturing food here in the Commonwealth, this guide can help.

This brochure is intended to help you answer the question, “How do I start a Food Manufacturing business in Kentucky?” You’ll find a brief overview of federal, state, and local rules and regulations, procedures, and suggestions about manufacturing food and cosmetics. Make special note of the hyperlinks to important web-sites that contain the rules, regulations, and guidance documents you need to make food legally—and safely.

A great place to begin for anyone thinking of starting a food business is the Food and Drug Administration (FDA) website:

<http://www.fda.gov/Food/ResourcesForYou/Industry/>

This site contains links to federal food laws and regulations, food labeling information and other useful resources for the food industry.

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. While most foods carry some risk of sickening customers if not properly prepared, certain kinds of foods can harbor bacteria and toxins that can result in serious, life-threatening illness! That is why both Federal and State laws are in place to regulate food production and distribution.

Kentucky's Food, Drug, and Cosmetic Act stipulates that "*No person shall operate a food processing establishment without having obtained an annual permit to operate from the Cabinet.*" Let's first consider the basic requirements for nearly all food manufacturers. Then, we'll take a look at some of the requirements for specific kinds of food.

Kentucky Food, Drug and Cosmetic Act
<http://www.lrc.ky.gov/krs/217-00/chapter.htm>

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! <http://www.foodsafety.gov/>

Regulatory Foundation

Food plants 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 foods and food products. This document can be accessed at:

<http://www.lrc.ky.gov/krs/217-00/chapter.htm>

The Kentucky Food Processing, Packaging, Storage, and Distribution Operations Regulation (902 KAR 45:160) is an administrative regulation that establishes procedures and requirements for food 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 firms, the regulation also contains food 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 plant inspectional frequency which is based on the degree of risk associated with the food commodity 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. The regulation can be accessed online at:

<http://www.lrc.ky.gov/kar/902/045/160reg.htm>

All Kentucky food plant operators should familiarize themselves with the provisions contained within both the Kentucky Food, Drug & Cosmetic Act and the Kentucky Food Processing, Packaging, Storage, and Distribution Operations Regulation.

New FDA Rules

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, a number of new rules related to FSMA are slated to be published in the Code of Federal Regulations this year and in 2016. The specific dates that food firms have to comply with the new rules is based upon the size of the operation.

The following five FSMA Final Rules have been published to-date, which could impact your operation:

- Preventive Controls for Human Food
- Preventive Controls for Food for Animals
- Standards for Produce Safety
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
- Accredited Third-Party Certification

Given the scope of these new 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. The website can be accessed at:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

A “Preventive Controls for Human Food” summary can be found at:
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

Fact Sheets on each of the final rules can be accessed at:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm>

Permits

You should begin by determining if your operation will be primarily wholesale or retail in nature. Generally speaking, if 75% or more of your product sales will be retail (direct-to-consumer), your manufacturing operation would be permitted and inspected through your local health department. There are exceptions to this, though. Establishments that do not have a retail store front that manufacture value-added packaged food products, or a firm that produces “high-risk” packaged items for retail sales (like pickled products) is subject to manufacturing rules. Food manufacturing operations that primarily wholesale their product (sales to another wholesale or retail outlet) or engage in internet sales are permitted and inspected through the KY Food Safety Branch. The permit fee schedule for food plants, including food processing, storage or distribution operations, is based on square footage, as follows:

<u>0-1000 Square Feet</u>	<u>\$120</u>
<u>1001-5000 Square Feet</u>	<u>\$160</u>
<u>5001-20,000 Square Feet</u>	<u>\$200</u>
<u>20,001 – 40,000 Square Feet</u>	<u>\$300</u>
<u>40,001 – 80,000 Square Feet</u>	<u>\$400</u>
<u>80,001 – 150,000 Square Feet</u>	<u>\$500</u>
<u>150,001 – or more Square Feet</u>	<u>\$600</u>

NOTE: Permits expire annually on December 31st.

Building and Fixture Requirements

- As a rule, every manufacturing facility must meet the following requirements:
- Be constructed of smooth, non-absorbent and easily cleanable materials and be designed to be insect/rodent-proof.
- Be connected to a municipal water source or have a water supply approved by the Division of Water (details follow).
- Be connected to a municipal sewer or an approved onsite septic system.
- Feature a hand wash sink in the food prep area, utensil wash area, and each restroom.
- Include a three-compartment sink with drain-boards for washing utensils.
- Have a utility/mop sink.
- Have restroom facilities approved by the KY Division of Plumbing, 502-573-0397, or <http://dhbc.ky.gov/PIb/Pages/default.aspx>

Please note that construction plans for new or renovated facilities, regardless of retail or wholesale operations, shall be submitted for review through the local health department.

You can find your Local Health Department here:

[http://chfs.ky.gov/dph/
LinkstoLocalHealthDepartments.htm](http://chfs.ky.gov/dph/LinkstoLocalHealthDepartments.htm)

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 to be 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.

Besides building a new commercial kitchen from scratch, there are several other options for meeting the requirements above. 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 office kitchens are all possibilities.

The KY 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 of your product will be manufactured there during times when the kitchen is not in use.

You may 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 for a current list of known, permitted co-packers here in Kentucky.

Water Supply

Wells, cisterns, springs and all other private water supplies must be approved by the Division of Water before they can be used in a food processing plant. Contact them at (502) 564-3410 or find them on the web at: <http://water.ky.gov/DrinkingWater>

Labeling

Packaged foods must have product labels that have been reviewed by the KY Food Safety Branch prior to their marketing. Product label inquiries should be directed to the attention of Paul C. Rice, who may be contacted at (606) 483-7185. All food manufacturing operations in Kentucky should be familiar with the following labeling information/rules:

FDA rules pertaining to the labeling of food products: <http://www.gpo.gov/fdsys/pkg/CFR-2008-title21-vol2/pdf/CFR-2008-title21-vol2-part101.pdf>

FDA's Food Labeling Guide:
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>

Did you know?

Many small-scale food manufacturers are exempted from the well-known Nutrition Facts Panel. The details for this exemption can be found here:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006867.htm>

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

- 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, shredded, etc.

- 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.

- 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: Ketchup (tomatoes, vinegar, high fructose corn syrup, onion powder....).

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

- Name and Address of the Manufacturer or Distributor

Shall include the street address, city, state, and zip code. If the company name as it appears on the label is listed in the phone book, then the street address may be left off.

When products are not manufactured by the name appearing on the label then use a statement such as “Manufactured for _____ ” or “Distributed by _____ ” to express the relationship.

*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, top of the package, etc.).

*The ingredient statement and name & address of the manufacturer or distributor can 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 6 pt font.

*A nutrition facts panel is not always required. If you use a statement that references a nutrient, like “Low Salt”, “No Sugar”, “Reduced Calorie”, “Low Fat”, “Low Cholesterol”, “High Fiber” then a nutrition facts panel is automatically required.

FDA Registration

▶ Bioterrorism Act

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 these requirements:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm331959.htm>

As part of the federal Bioterrorism 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. The complete BT Act and related information can be found at the following internet address:

<http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm>

▶ 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.

For more information regarding the Reportable Food Registry, please refer to:

<http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>

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 one helpful:

An Introduction to Food Security Awareness online training course; available at:

<http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm120929.htm>

Kentucky Business One Stop Portal

Besides those 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.)

<http://onestop.ky.gov/Pages/default.aspx>

Now that we've discussed the basic requirements for all manufacturing operations, let's take a closer look at some operations which have special requirements. *Remember, this info is not intended to cover everything.* Consulting with a Food Scientist or Area Inspector from the Food Safety Branch is the best way to ensure a safe, approved product!

The science of food processing can be highly complicated. Every day, we learn more and more about what causes foodborne illness and how to prevent it. But, monitoring a few basic factors in food safety can keep most foods safe. These are:

Acidity (low pH)

Water Activity (a_w)

Temperature

Oxygen

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

Low-Acid 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. The process of pickling food to preserve it is thought to be about 4000 years old. Some believe the first pickles were made when foods were placed in sour wine. In any event, pickling—when done properly—is an excellent way to preserve safe, wholesome, and tasty vegetables.

Scientifically speaking, acidifying—or pickling—is the use of an acid (commonly vinegar, aka acetic acid) to reduce the pH of a product to below 4.6. This is a “magic number” because most bacteria won’t survive in foods that are this acidic.

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 that “magic” pH of 4.6. *C. botulinum* is not viable in food that has an acidity of 4.6 or less. That is what makes pickling—when done correctly—such an effective way of preserving food.

But what about canning vegetables that aren’t pickled? 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 things like pepper (or other herb & vegetable) jellies, too.

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

- 1) First, successfully complete an approved Better Process Control School (BPCS). The following pages list some organizations that provide BPCS training. Or, contact the KY Food Safety Branch to check on any upcoming local classes.

2) Second, have all recipes reviewed and approved 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. Note that these reviews are conducted by private industry, and usually require a fee. In the following pages, we’ve included a few known Process Authorities that operate in Kentucky. However, this list is not meant to be exhaustive

Better Process Control Schools (BPCS)

UK's Food Systems Innovation Center

<http://www.uky.edu/fsic/>

Grocery Manufacturers Association

http://www.gmaonline.org/file-manager/Events/Bro_BPCS-011411.pdf

University of California at Davis' Online BCPS

<http://ucfoodsafety.ucdavis.edu/Better-Process-Control-School-Online/>

University of Tennessee Extension

<https://ag.tennessee.edu/foodscience/Pages/Better-Process-Control-School.aspx>

Purdue University

<https://ag.purdue.edu/foodsci/extension/Lists/workshops/DispForm.aspx?ID=7&ContentTypeId=0x01004B29D0ACB9C4D24FB8C16BECDDC40AD8>

Process Authority Search

The Association of Food and Drug Officials (AFDO) website 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 <http://www.afdo.org/foodprocessing> .

- For Kentucky specific assistance, please contact the University of Kentucky Food Systems Innovation Center (859) 257- 7272 x286
www.uky.edu/fsic

Seafood & Shellfish

Being 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 <http://fw.ky.gov/Pages/default.aspx>

Seafood

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

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: <http://www.fsis.usda.gov/wps/wcm/connect/45f61995-b867-4a5b-a4e0->

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

SEAFOOD HACCP

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

It was because of these requirements that the National Seafood HACCP Alliance was formed in 1997. Led by the University of California— Davis and the Association of Food & Drug Officials (AFDO), the Alliance was designed to help regulators and seafood producers understand and use HACCP principles. The Alliance hosts the first segment of training on its website at:

<http://seafoodhaccp.cornell.edu/Intro/index.html>

The second segment of the course is a classroom exercise held in many places across the country. Kentucky processors should contact Diane McDaniel of FDA for the nearest course. Her number is (614) 227-5780, x107.

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:

<http://www.lrc.ky.gov/kar/902/045/020.htm>

The 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:

<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm>

For more information regarding the Shellfish Dealers program, contact Paul C. Rice, Kentucky State Standardized Shellfish Officer, at (606) 424-0190.

Meats & Poultry

Kentucky is proud to be the largest beef producer east of the Mississippi River and the fourth largest farming state in the nation. It comes as no surprise, then, that we receive many questions on what regulations govern meat processing, warehousing, and sales.

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 production plants will require permits from both the USDA and the KY Food Safety Branch. This is because 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.

In any event, if you plan to process and sell home-grown meat or make a product that contains meat, your first contact should be:

USDA, FSIS, FIELD OPERATIONS
Jackson District Office
713 S Pear Orchard Road
Suite 402
Ridgeland, MS 39157
(601) 965-4312

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.”

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 KY 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. (See pages 7-9.) 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 Procedures (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.

Did you know?

Kentucky's #1 agricultural commodity (excluding horses) is poultry! The poultry industry employs 7000 Kentuckians and buys 29% of the state's grain crops!

Rabbits

Some meat 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.

The requirements for processing rabbits-or any other Non-amenable Species are essentially the same as for poultry: separated kill and processing rooms, approved plumbing, and manufacturing permit. Rabbit processors must also conduct Hazard Analyses, develop HACCP Plans, and implement SSOPs. However, they do not need to bear a USDA-exempt statement as poultry does. These basic rules would apply to any of the other non-amenable, as well.

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

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/small-and-verysmall-plant-outreach>

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 is NOT regulated by the Food Safety Branch. Instead, you must obtain a license from the Kentucky Department of Agriculture. Note that there are ~~types~~ of Egg Licenses: retail (for direct-to-consumer sales) and wholesale (for sales to groceries, restaurants, etc.) To get either of these permits, you must visit the Kentucky Department of Agriculture website at www.kyaqr.com.

At the home page, click on programs→Licensing & Laws →Egg Marketing. On the left you will see a link to all the egg forms. Download, complete, and return to the address on the application along with your check or money order for \$20.00.

If you have specific questions, you may contact Heath Higdon or Josh Glass at (502) 573-0409.

Syrup, Sorghum, and Honey

Sorghum and Maple Syrup:

Individuals who produce less than 4,500 pounds, 500 gallons, or \$6,000 per year (whichever is least), are not usually required to obtain a commercial permit. However, they must properly label their product. Product labels should be submitted to for review to:

Paul C. Rice
Food Safety Branch
275 E. Main Street, HS1C-F
Frankfort, KY 40621

Honey

House Bill (HB) 400, signed into law and effective beginning on July 16, 2002 contains specific exemptions for some honey producers. Specifically, the law states that if a person sells less than one hundred fifty (150) gallons of honey in a year off the farm, the person is not required to process the honey in a certified honey house or food processing establishment. This exemption is equivalent to less than 1800 pounds of honey per year. Apiaries meeting this exemption would still need to comply with Kentucky's labeling requirements and operate in a safe and sanitary manner. Product labels should be submitted to for review to:

Paul C. Rice
Food Safety Branch
275 E. Main Street, HS1C-F
Frankfort, KY 40621

Labels

Labels for honey containers, as for all foods in Kentucky, are also regulated by the Department for Public Health, Food Safety Branch. The requirements for honey labels are detailed below.

For the most current FDA draft guidance on the labeling of honey products see this link:

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm389501.htm>

Identity of the product: HONEY

- Net Quantity: For honey this is customarily stated in weight - ounces and grams, not volume.
- A *one pound* jar label should state Net Wt. 1 lb (454 g).
- A *two pound* jar should say Net Wt. 2 lb (908 g).
- A *one pint* jar should say Net Wt. 22 ounces (624 g) or Net Wt. 1.37 lb (624g).
- A *one quart* jar should say Net Wt. 44 ounces (1.2 kg) or Net Wt. 2.75 lb (1.2kg).
- 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 with your name.

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

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 KY Food Safety Branch. However, if you intend to manufacture ice cream from ‘scratch,’ you’ll need to contact the KY 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.

Did you know?

According to the KY Dairy Development Council, an average dairy cow generates \$13,700 for KY’s economy every year. Kentucky currently has nearly 75,000 head of dairy cattle. This means Kentucky dairies contribute over \$1 Billion to our state economy!

Pet Treats

Pet treats—and all other animal food—are regulated by the University of Kentucky's Division of Regulatory Services. You may contact them at (859) 257-2785 or see their website at:

http://www.rs.uky.edu/regulatory/feed/pet_treats/

Products Containing Alcohol

For manufacturers of products containing more than 1% alcohol, jurisdiction must be verified by the appropriate alcoholic beverage control authorities. This applies to ANY product—liquid or otherwise.

The process begins at the FEDERAL level. The US Alcohol and Tobacco Tax and Trade Bureau determines whether a product is considered an alcoholic beverage or a “non-beverage product.” This website will direct you to the lab that makes these determinations:

<https://www.ttb.gov/industrial/mnbp.shtml>

Once you've received a Federal classification, you'll need to contact the Kentucky Department of Alcoholic Beverage Control. For more information, please contact them at (502) 564-4850 or see their website: <https://abc.ky.gov/Pages/index.aspx>. You will find an application to produce “non-beverage products” here:

Juice & Cider

Depending on the details of a specific operation, most juice and cider manufacturers are subject to FDA's Juice HACCP regulation. Similar to 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 it carefully.

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm>

Bottled Water

Obtaining a permit to bottle water in Kentucky is a two-step process. 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.

Their website provides contact information, links to Drinking Water Regulations, and other helpful information for potential bottlers:

<http://water.ky.gov/permitting/Pages/DrinkingWaterPlansReview.aspx>

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.

FDA requires that bottled water manufacturers test source water for total coliform and determine whether any coliform organisms that may be found are *Escherichia coli* (*E. coli*). Before a bottler can use water from a source that has tested positive, the bottler must take eliminate the cause of *E. coli* contamination of that source. Additionally, records of source water treatment must be kept.

If any coliform organisms are detected in finished bottled water products, that bottled water manufacturer determines whether any of the coliform organisms are *E.coli*. Bottled water containing *E. coli* will be considered adulterated, and source water containing *E.coli* will not be considered safe enough for use in bottled water.

For more information, please see FDA's Guidance for Industry document, *Bottled Water: Total Coliform and E.coli; Small Entity Compliance Guide*, available at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/BottledWaterCarbonatedSoftDrinks/ucm206215.htm>

The Federal Bottled Water regulation, 21 CFR 129—Processing and Bottling of Bottled Drinking Water; is available at:

<http://www.gpo.gov/fdsys/pkg/CFR-2008-title21-vol2/pdf/CFR-2008-title21-vol2-part129.pdf>

Produce

Wholesale produce warehouses must obtain a Warehousing permit from the Food Safety Branch prior to operation. Processing produce by peeling, slicing, mixing, bagging, etc. will require a Manufacturing permit. Washing produce to market the product as “ready-to-eat” will also require a Manufacturing permit.

All produce growers, shippers, and retailers are expected to use Good Agricultural Practice principles to ensure a safe, nutritious product.

Kentucky Department of Agriculture has some excellent reference documents on Good Agricultural Practices for specific commodities. You can find that information here:

<http://www.kyagr.com/marketing/GAP-resources.html>

Salvaged Foods

Specific requirements for your operation are dependent upon whether or not your business is processing or just distributing salvaged foods. In any event, both Salvage Processors and Salvage Distributors must obtain a permit prior to commencing operation.

Operations that sort, cull, or clean-up of some or all of the merchandise they receive shall be required to obtain a Salvage Processor permit. This includes any business that receives boxes of co-mingled salvage or distressed food products from out-of-state salvage/liquidation companies. Salvage Processors obtain this permit directly from the Food Safety Branch— Manufacturing Section.

On the other hand, Salvage Distributors must only purchase already processed merchandise from within the state, for resale. Their permit comes from the Local Health Department in the county or district where they are located. If product is purchased from outside the state, a processing permit is required.

Section 7(1) of the State Food and Cosmetic Salvage Regulation (902 KAR 45:080) stipulates that "all salvageable distressed merchandise shall be reconditioned prior to sale or distribution except for such sale or distribution to a person holding a valid salvage processing permit issued by the cabinet."

In addition, Section 4 of this regulation requires damaged or distressed merchandise in the possession of wholesale food warehouses or distributors, food processors, etc., and retail food stores to be sold or transferred only to a person who holds a valid Salvage Processor permit.

Please note that the sale of outdated over-the-counter medications is prohibited among all food establishments, including salvage processors/distributors. Such products are considered adulterated and subject to quarantine. Likewise, firms possessing such products with the intent to redistribute or resell them may be subject to enforcement action.

The State Food and Cosmetic Salvage Regulation sets the rules regarding handling, transporting and selling distressed, salvageable or salvaged foods. You can view this regulation at:

<http://www.lrc.ky.gov/kar/902/045/080.htm> .

Cosmetics

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

Cosmetics manufacturing operations are permitted and inspected through the KY Food Safety Branch and/or the Food and Drug Administration (FDA). All cosmetics manufacturers are subject to the same fixture/structural and permit requirements as food plants (see pages 9-12).

The KY Cosmetic Packaging and Labeling Regulation is available at:

<http://www.lrc.ky.gov/kar/902/045/060.htm>

These links will be useful to anyone who wants to manufacturing cosmetics:

From FDA:

Cosmetic Labeling Manual,
<http://www.fda.gov/cosmetics/labeling/regulations/ucm126444.htm>

Guidance for Industry: Cosmetic Processors and Transporters Cosmetic Security Preventive Measures Guidance; available at:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082716.htm>