Commercial Food

Manufacturing in

 Kentucky:

A Starter Guide



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

1. Review the section of this Guide which

co­vers that product

1. Locate a commercial-grade facility that meets building requirements (pg. 7)
2. Contact your area inspector to set up an opening inspection (see map on pgs. 42- 43)
3. Demonstrate your process and provide a draft label (pg. 10) at your opening inspec­tion
4. 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.

 entucky 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:

0-1000 Square Feet $120

1001-5000 Square Feet $160

5001-20,000 Square Feet $200

20,001 – 40,000 Square Feet $300

40,001 – 80,000 Square Feet $400

80,001 – 150,000 Square Feet $500

150,001 – or more Square Feet $600

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/Plb/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/%20%20LinkstoLocalHealthDepartments.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](http://water.ky.gov/%20DrinkingWater)

**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/GuidanceDocumentsRegulatoryInfor-mation/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 state‑

ment 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 (aw)

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/Bet-ter_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](http://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-](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](http://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/](http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm)

[FederalStateFoodPrograms/ucm2006753.htm](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-amenables, 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](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/small-and-very-small-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 *two types* of Egg Licenses: retail (for direct-to­consumer 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.kyagr.com](http://www.kyagr.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/GAP­resources.html](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*](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/GuidanceDocumentsRegulatoryInfor-mation/FoodDefense/ucm082716.htm>