



Understanding the U.S. Food Safety Regulatory System

Paul Priyesh Vijayakumar¹, Badrinath Vengarai Jagannathan² and Mari Schroeder³

The Basics of Food Law and Regulation

Food producers need to understand the food laws and regulations that are there to protect the well-being of the consumers of their products. These laws and regulations help to ensure that foods are safe and free from adulteration, meaning they are free from physical, chemical and microbial hazards. Foods must also have accurate labels, which can help the consumer know exactly what is in their purchased product so that they can make informed decisions. In order for food producers and consumers to understand the laws and regulations that have been put in place, it may be useful for them to be able to first differentiate between a law and a regulation, as well as the different branches and divisions that create, pass and enforce them.

A law is a broad policy or statement of intent, while a regulation consists of the details of how the policy or statement of intent is implemented. All federal laws are listed in the U.S. Code (USC) and the regulations can be found in the Code of Federal Regulations (CFR). The CFR is slightly more complicated in that Title 21 consists of the Food and Drug Administration's (FDA) regulated foods and Title 9 encompasses all of the United States Department of Agriculture's (USDA) regulated foods (these departments will be explained later on). All laws must be passed or amended by the legislative branch before being enforced by regulations created by the executive branch. As a way to make sure that all laws and regulations are being followed there is the judicial branch that reprimands any violations.

Because there are many types of products, processes and services in respect to food, there are several different agencies that focus on specific areas. It is congress that specifies which agency will have jurisdiction and if any laws or regulations need to be created. The different agencies are listed below:

Department
Food and Drug Administration (FDA)
U.S. Department of Agriculture (USDA)
Environmental Protection Agency (EPA)
Federal Trade Commission (FTC)
U.S. Department of Commerce (USDC)
Public Health Service (PHS)
Bureau of Alcohol, Tobacco, and Firearms (BATF)
U.S. Department of Labor (USDL)

*It is important to remember that “non-exempt” food manufacturers, including those not engaged in interstate commerce, are required to register with FDA as part of the Bioterrorism Act of 2002. One can do this online at: <http://www.access.fda.gov>, or by paper: Form 3537.

The FDA is responsible for most food manufacturing operations that are engaged in “interstate commerce” and regulates 80% of the U.S.’s manufactured food products that contain less than 2% raw and less than 3% cooked meat or poultry, fish or other seafood. The

FDA has also developed Current Good Manufacturing Practices (CGMPs). CGMPs are sanitary procedures to reduce safety risks, microbiological standards, the design of facilities, production controls and proper handling of ingredi-



¹Paul Priyesh Vijayakumar is the Food Safety Specialist in the Animal & Food Sciences Department at the University of Kentucky

²Badrinath Vengarai Jagannathan is a PhD candidate in the Animal & Food Sciences Department at the University of Kentucky

³Mari Schroeder is a Graduate Research Assistant in the Animal & Food Sciences Department at the University of Kentucky

Table 1. List of agencies with their corresponding responsibilities

Agency	Responsibility
Food Safety Inspection Service (FSIS)	Oversees meat and poultry inspection, approves mandatory HACCP plans.
Food and Nutrition Service (FNS)	Manages donated and other public food programs.
Agricultural Research Service (ARS)	Oversees research in agricultural production and product utilization.
Federal Grain Inspection Service (FGIS)	Sets grain standards and does grain inspection.
Agricultural Marketing Service (AMS)	Sets and evaluates grade standards for a variety of foods.

ents and raw materials to minimize the risk of food-borne illnesses. In addition to developing CGMP, the FDA has received new regulatory powers through the Food Safety Modernization Act (FSMA).

For products that contain more than 2% raw meat or poultry, or if the meat products are pre-packaged and intended for wholesale or interstate commerce then the responsibility is handed over to the USDA. The USDA does not regulate any products containing more than 2% fish, seafood, rabbit or any other non-amenable species. The USDA also regulates processed eggs, inspects every carcass of poultry, beef, pork and other edible animals. Laws that govern the USDA include the Meat Inspection Act, the Poultry Inspection Act, the Egg Products Inspection Act and the U.S. Grains Standards Act. The USDA has several different agencies located within the department and they are listed above in Table 1.

Risk Types

The term “risk” indicates the difficulty of safe processing, the history of outbreaks, and the safe storage requirements associated with a certain product. Products can be organized into three different categories: low risk, medium risk, and high risk. Low Risk products require the least amount of regulation and extend to products with either a low moisture content (i.e. dried spices, tea, coffee, and pasta) or contain high amounts of sugar (i.e. jams/jellies, honey, and breads). Medium risk products require a bit more regulation along with special training and include acidic foods (i.e. BBQ sauces, ketchup, and mustard) or acidified products (i.e. pickles, sauerkraut, and vinegars). High risk products require the most regulation and also include special trainings. These products include food packaged in vacuum-sealed containers, juices, seafoods, high pH foods (cucumbers) that are acidified (pickles), and low-acid canned foods (LACFs) like canned vegetables, and sugar-free jams/jellies.

The special training for medium- and high-risk products includes the Hazard Analysis and Critical Control

Points (HACCP), and the Better Processing Control School (BPCS). The BPCS for acidified food is offered through the University of Kentucky’s Food Systems Innovation Center several times a year. Dates and times can be found using the following link: <http://www.uky.edu/fsic/>.

Food Safety in Kentucky

In addition to federal oversight of food production in the United States, there are regulations and oversight specific for Kentucky. These agencies include the Kentucky Food Safety Branch, Kentucky Division of Plumbing, Kentucky Division of Water, Local Health Department and Local Planning and Zoning; their responsibilities are listed in Table 2 (see next page).

Basic Requirements for “Commercial” Facilities in Kentucky

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 drainboards for washing utensils.
- Have a utility/mop sink.
- Have restroom facilities approved by the KY Division of Plumbing, or <http://dhbc.ky.gov/Plb/Pages/default.aspx>.
- Obtain a Permit to Operate from the Regulatory Agency (LHD or Food Safety Branch State Health Department).

All materials listed are for general information purposes only to help you learn more about the basic requirements of a commercial facility. The information presented is not legal advice, is not to be acted on as

Table 2. Kentucky specific agencies and responsibilities

Agency	Responsibility
Kentucky Food Safety Branch	Responsible for the safety of all manufactured food products produced in Kentucky, already inspected by the USDA. Also it oversees LHD (Local Health Department) Inspections of retail food establishments across the state, while operating under the authority of the Kentucky Food, Drug and Cosmetic Act.
Kentucky Division of Plumbing	Responsible for enforcing the Kentucky Plumbing Code that has very specific regulations for plumbing in all food facilities. Before any retail food or food-manufacturing permit will be issued, approval from plumbing must be received. For convenience, there are plumbing inspectors at each local health department or district. They can be located at http://dhbc.ky.gov/Plb/Pages/IC.aspx .
Kentucky Division of Water	Contact division of drinking water: (502) 564-3410 or https://eec.ky.gov/Environmental-Protection/Water/Pages/default.aspx for more information.
Local Health Department	Primarily responsible for retail food: groceries, restaurants, schools, Farmers Markets, etc. Permits to firm that want to cook food for sale to the public (temporary food service) is issued here, as well as retail sales permits for food sold directly to the consumer. Contact https://chfs.ky.gov/agencies/dph/dafm/Local%20Health%20Department%20Information/AlphaLHDListing.pdf for more information.
Local Planning and Zoning	It is often overlooked by folks interested in building their own kitchens or food manufacturing facilities, but should be one of the first agencies to consult if building a ‘brick-and-mortar’ facility or opening a business in a private residence. It should be noted that variances can be difficult to obtain in certain areas.
Kentucky Department of Agriculture	The Kentucky Department of Agriculture Office of Agricultural Marketing assists farmers, agricultural businesses, and commodity groups in promoting and marketing their products by expanding existing markets, as well as developing domestic and international markets. In 2018, KDA was approved for federal funding to staff, develop and execute an inspectional program on behalf of FDA for the Produce Safety Rule portion of the Food Safety Modernization Act. For more information visit http://www.kyagr.com/marketing/produce-safety.html or contact Ben Conner, Produce Safety Program Manager, 107 Corporate Dr., Frankfort, KY 40601, Office - (502) 782-7809, Mobile (502) 229-1914.

such, may not be current and is subject to change without notice. For comprehensive requirements please refer to the manual by using the following link:
http://www.kyagr.com/marketing/documents/FM_Commercial_Food_Manufacturing_in_Kentucky.pdf

Labeling

All packaged foods must have proper product labels, which are reviewed prior to marketing as some exempt products need not carry the Nutrition Facts Panel. For label compliance review, contact a label review specialist: (502) 564-7181.

The Basics for Meat Production

Due to the risk factors associated with meat production, there are many different departments and agen-

cies that regulate it. Manufacturers must provide an office, telephone, computer, and Internet access for this inspector as well as pay the hourly rate for inspection of the USDA-regulated product. This only applies to any pre-packaged “amenable” meat product meant for wholesale. There specific rules and exceptions to certain products and they are as follows:

- Poultry - it is usually under the jurisdiction of USDA, but there are certain exemptions from the USDA that place poultry production under the Kentucky Food Safety Branch. USDA “Exempted” poultry plants in KY would have the same minimum facility requirements as any other food plant and more. Poultry must be processed under a HACCP plan.
- Rabbits - they are NOT regulated by USDA, but

are under the jurisdiction of the Kentucky Food Safety Branch. They too have the same minimum requirement of any other firm and more, and must be processed under a HACCP plan.

The fact sheet on meat inspection can be found using the following link: https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/inspection-and-grading-of-meat-and-poultry-what-are-the-differences_/inspection-and-grading-differences.

The Basics for Dairy Foods

Dairy in Kentucky is regulated by the Kentucky Milk Safety Branch and follows the FDA's Pasteurized Milk Ordinance (PMO). This includes milk and creamers, cheeses and real ice cream. The PMO requires that all milk products are pasteurized and apply the same plumbing code rules as any other food-manufacturing establishment. For more information, contact Lewis Ramsey, Branch Manager at (502) 564-3340.

Commercial Egg Production

Egg production is regulated by Department of Agriculture, Consumer Protection Service. It covers farms that produce more than 60 dozen eggs/week, and all retail establishments that sell eggs or egg products. For more information, contact the Kentucky Department of Agriculture: (502) 573-0409.

Bottled Water

Water is regulated by the shared jurisdiction of the Kentucky Food Safety Branch, and the Division of Water, Energy and Environment Cabinet. The Division of Water must approve source water and treatment (<https://eec.ky.gov/Environmental-Protection/Water/Drinking/Pages/Drinking%20Water.aspx>) and requires regular pre- and post-treatment tests. The Kentucky Food Safety Branch permits any bottling operations.

Rules and Regulations for Home-Based Processing Programs

House Bill (HB) 391 created the Home-Based Processing Program "Farmer Friendly" legislation for those who were the "exceptions" to the normal (commercial) Food Manufacturing Program requirements. HB 391 allows specific foods to be made in the farmer's home kitchen and sold to the public **only at cer-**

tain locations listed below. There are two classes of food products and processors noted in HB 391, Home-based Processors and Home-based Microprocessors, within the Home-Based Processing legislation. The first class of processor is the **Home-based Processor**; this includes low risk products such as dry herbs, jams, jellies, baked goods, and syrups. These products carry minimal risks in regard to foodborne illnesses. House Bill 263, an Act relating to home-based food products became law on July 14th, 2018. HB 263 allows a Kentucky resident to produce or process whole fruits and vegetables, mixed-greens, jams, jellies, sweet sorghum syrup, preserves, fruit butter, bread, fruit pies, cakes or cookies in their home kitchen **without being permitted or registered.** However, a home-based processor may be inspected annually by the Cabinet for Health and Family Services and shall be subject to food sampling and inspection if it has been determined that a product is misbranded, adulterated, or a consumer complaint has been received. The Cabinet also has the authority to put a hold on production if there is reason to believe that the food product presents an imminent health hazard until that hazardous situation has been addressed appropriately. A home-based processor will not have to grow a primary ingredient, but is required to ensure that all finished product containers are clean, sanitary, and properly stored, and that all glass containers for jams, jellies, preserves, fruit butter, and similar products are provided with suitable rigid metal covers. In addition, all home-processed foods cannot be adulterated or misbranded. These home-based processed food items may be sold directly to consumers within this state, including from the home-based processor's home by pick-up or delivery, at a market (not a permitted retail market), a roadside stand, and a community event or online. It should also be noted that the products listed above will not require testing to determine whether or not the food product is an acid food, acidified food product, formulated acid food product, or low-acid food.

The home-based processing program will be administered by the Food Safety Branch. If you have any questions, complaints, etc. related to home-based processing please forward those to the Food Safety Branch. The Food Safety Branch is working with its legislative liaison to update the Kentucky Administrative Regulations (KAR) and will forward these changes and post them on the Food Safety Branch website.

Table 3. Food products based on risk type, locations allowed for sale, and regulating agency/program

Product Type	Approved Locations to Market Home-Based Products	Prohibited Locations	State of Kentucky KY-DPH, Food Safety Branch Regulatory Training Requirements
Low-Risk Products - Fruit Pies, Syrups, Jams, and Jellies	<ul style="list-style-type: none"> • Farm • Farmers Market Listed with KDA • Online • ONLY IN STATE OF KENTUCKY 	<ul style="list-style-type: none"> • Restaurants • Grocery Stores • Retail Markets • Gift Shops • Wholesale • Mail Order Sales • Interstate Sales 	Home-Based Processor Program
Higher Risk Products - Home-Canned Pickles and Pressure-Canned Vegetables, Relishes	<ul style="list-style-type: none"> • Farm • Farmers Market Listed with KDA • Roadside Stands Certified by KY Farm Bureau 	<ul style="list-style-type: none"> • Restaurants • Grocery Stores • Retail Markets • Gift Shops • Wholesale • Mail Order Sales • Internet Sales • Interstate Sales 	Home-Based Microprocessor Program
Jams/Jellies and/or Pickled Products (Acidified) (Manufactured Foods Permit)	<ul style="list-style-type: none"> • Restaurants, Groceries, and Gift Shops • KY Proud Stores • Wholesale • Interstate • Via Internet, Farmers Market & Roadside Stands 		<ul style="list-style-type: none"> • FDA Requires – <u>Better Process Control School Certificate</u> • KY-DPH Commercial Permit • Manufacturing Process Reviewed by a <u>Process Authority</u> • Register Facility with FDA • Fill out form 2541e for FDA’s approval

The second class of processors is the **Home-based Microprocessors**; these include the higher risk products such as pickles, salsas, and canned vegetables. This second class of products is classified as high risk due to their potential to create an environment for pathogens if processed incorrectly. In order for a producer to be qualified for the **Home-Based Microprocessing Program** they **must** be a “Kentucky Farmer” who is

a resident and owns or leases farmland that produces the primary ingredients for the product they wish to produce under this legislation. The producer must also process or manufacture a product that contains a primary or predominant Kentucky-grown agronomic/horticultural ingredient, grown, harvested, processed, and marketed by the farmer. In addition, they **must** successfully complete a microprocessor workshop,

possess verification of approved water source, have a standardized recipe for each product reviewed and approved by the HBMP program of UK Extension, have product labels reviewed, and have a complete application. **Registrations and certifications are NOT transferable and if a producer wishes to make both types of products they must complete an application for each category.** Only *after* Home-Based Processors and Microprocessors have registered with the Cabinet can they begin to process their products. Note that there is no fee for processor registration by the Department of Public Health, but there is a \$50 fee for Microprocessor certification by the Department of Public Health. The table above summarizes what types of products are accepted, where exactly they can be sold and the type of special training that is required for certain products.

Home-Processed foods MUST be labeled with the following information in 10-point type:

- The phrase, “**This product is Home-Produced and Processed**”
- Name and address of the producer
- Ingredients, listed in descending order of predominance by weight
- Net weight
- Date processed

For any canned food products sold beyond the home-based processor and microprocessor certified outlets, process reviews are required for the products by the FDA and KY Food Safety Branch. If you would like to submit any products for process review, please use the following link: KY Process review - http://www.uky.edu/fsic/forms/Process_Review_Submission_Formr.pdf. Qualified Process Authority in Kentucky - Paul Priyesh Vijayakumar, Ph.D.

Produce Safety Programs and Guidance

In an effort to minimize the risks associated with raw food products, there are two different safety programs specifically for produce production and handling. The first program is the All-Samples Certificate and it is an online training assessment for producers offering raw samples to the customers. It is **required** for those producers wishing to give samples of their products at farmers markets or roadside stands. This is NOT voluntary and requires the applicants to take the Produce Best Practices Training (PBPT) to be eligible to apply for an All-Samples Certificate (PBPT trainings are hosted by the University of Kentucky Cooperative

Extension Service). The newest program to impact produce production and handling in Kentucky, the United States, and the world is the Food Safety Modernization Act – Produce Safety Rule (FSMA-PSR). FSMA-PSR is a federal regulation that is required by law. The level of coverage or oversight under FSMA is dictated by annual sales of produce, food, the buyer, and its intended end use. Not all farms growing produce will be covered by the Produce Safety Rule. A variety of factors must be taken into account, such as changes in annual sales, changes in the type of crops being grown, who is purchasing the crops, where the buyer is located in relationship to the farming operation, what is the intended use of the crop, just to name a few things that must be considered. To find out if FSMA-PSR applies to you, please visit the following link to access the FSMA-PSR tool and complete the survey: https://uky.az1.qualtrics.com/jfe/form/SV_9oQEXqziH1yYmdD. To ensure that farms are following regulations, the FDA will periodically make assessments through inspections. It is also highly recommended that these farms develop a food safety plan/manual. For more detailed information about the Produce Safety Program or about guidance, please visit the links below.

- Understanding a Produce Safety Program and Marketing a Food Safety Plan - <http://www2.ca.uky.edu/agcomm/pubs/IP/IP78/IP78.pdf>
- GAP Program - <http://www.kyagr.com/marketing/GAP-resources.html>
- Produce Safety Program - <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- Center for Crop Diversification – Produce Food Safety - <http://www.uky.edu/ccd/food-safety>

Third Party Good Agricultural Practices (GAP) Audit and Good Handling Practices (GHP)

Third Party Good Agricultural Practices audits (GAP Audit) and Good Handling Practices Audits (GHP Audit) are a voluntary food safety practices regimen dictated by business-to-business transactions. Some wholesale buyers will require farms to be GAP/GHP certified before being willing to buy their products. **Unlike the other regulatory programs mentioned in this document, GAP is NOT dictated by government regulation, law or oversight.**

Contact the Authors:



Paul Priyesh Vijayakumar

paul.v@uky.edu

859-257-1546

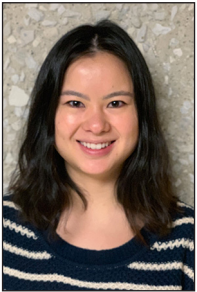


Badrinath Vengarai

Jagannathan

badrivj@uky.edu

859-218-4384



Mari Schroeder

mari.schroeder@uky.edu

859-257-3855

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1. Kentucky Department Of Agriculture - http://www.kyagr.com/marketing/documents/FM_Manual_and_Resource_Guide.pdf
2. Kentucky Food Safety Branch - <https://chfs.ky.gov/agencies/dph/dphps/fsb/Pages/default.aspx>
3. The United States Department of Agriculture (USDA)
4. The United States Food and Drug Administration (FDA)

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