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# Starting a Food Manufacturing Business in Tennessee:

## Summary of Food Manufacturing Regulations and Resources

September 2021


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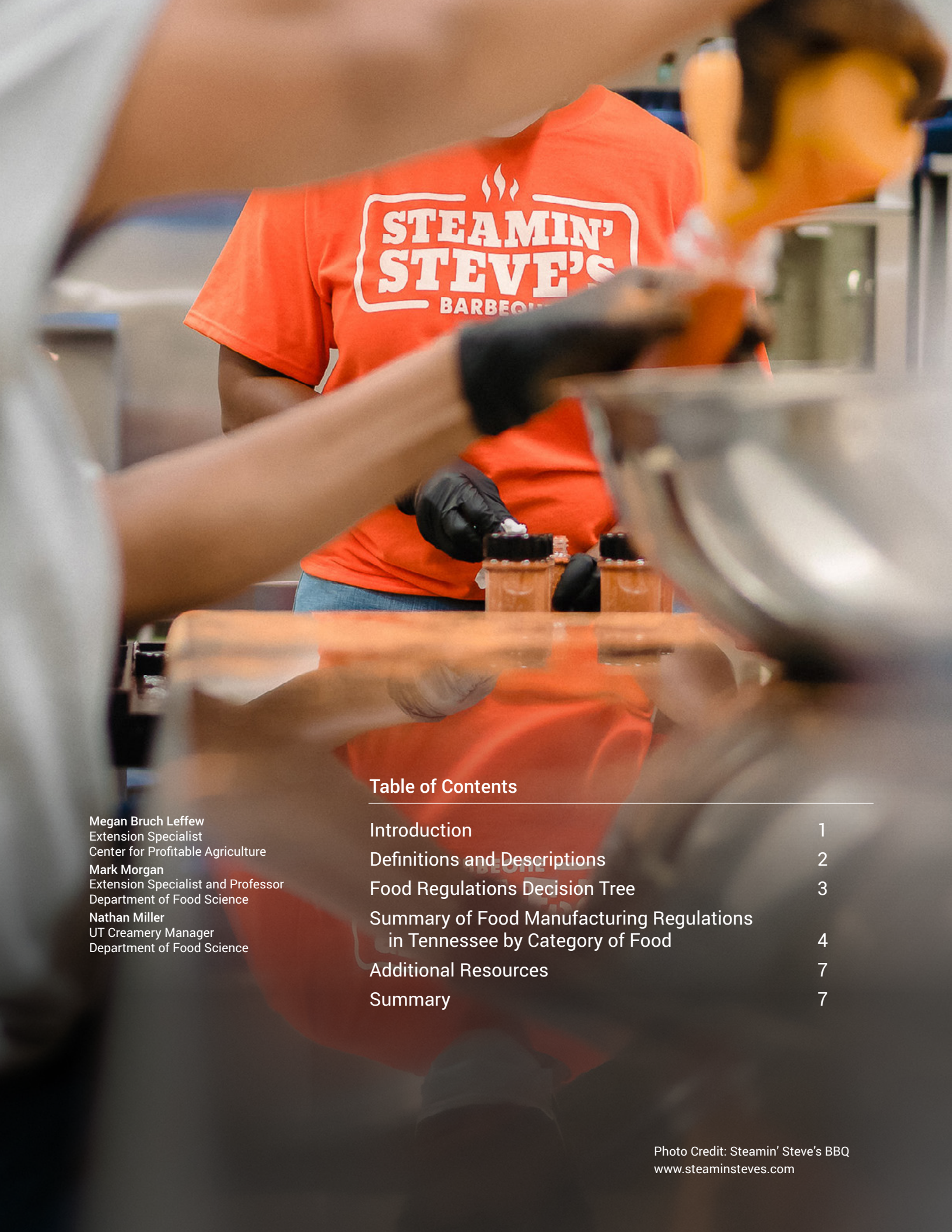


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www.steaminsteves.com

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## Introduction

Identifying which food manufacturing regulations apply to specific products can be difficult for Tennessee farmers interested in adding value to their farm products and to entrepreneurs interested in manufacturing foods. Regulations vary depending upon: 1) the level of food safety risk of the product and 2) how/where the product is sold or distributed. Foods manufactured for sale in Tennessee may be regulated by the Tennessee Department of Agriculture (TDA), United States Department of Agriculture (USDA), and/or the United States Food and Drug Administration (FDA). Food prepared for on-site consumption such as for a concession stand, food truck, catering or restaurant are regulated by the Tennessee Department of Health and/or your local health department.

This fact sheet provides a decision tree to help producers and food manufacturers identify whether their plans are considered food service or food manufacturing and whether a food manufacturing permit and commercial kitchen are required. A basic summary of the major food manufacturing regulations by category and additional resources are provided to help Tennessee producers, industry partners and other potential food manufacturers identify the regulations and regulating agency(ies) involved in the process.

Categories of manufactured foods covered in this summary include:

1. Non-potentially hazardous foods manufactured under Tennessee Cottage Food Law
2. Potentially hazardous foods, Time/Temperature Control for Safety (TCS) foods and non-potentially hazardous foods not covered by Cottage Food Law
3. Formulated acid foods
4. Acidified foods

This fact sheet does not include information related to livestock or meat processing, retail meat stores/butcher shops, beef jerky or other meat products or dairy products such as fluid milk, cheese, ice cream, yogurt, etc. Regulations for these food categories are specialized and vary dramatically from the product categories included in this fact sheet. This publication also does not cover the nuances of food manufacturing performed within retail food establishments. The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers.

Photo Credit: Tennessee Department of Agriculture

## Definitions and Descriptions

Definitions and descriptions of key terms used in this fact sheet are provided below:

- **Non-potentially hazardous foods** – This term is not clearly defined in any regulation. It is intended, however, to identify foods that do not require refrigeration and are shelf stable because they a) have very low water activity, b) have very low pH or c) a combination of both. Low water activity and/or low pH will prevent harmful bacteria from growing in the food. Many baked goods, jams, canned fruits and dry herbs or spice blends are non-potentially hazardous.
- **Potentially-hazardous foods** — Potentially hazardous food are those foods which consist of meat, poultry, liquid eggs and partially cooked egg products, fish, milk and milk products, shellfish, partially cooked bakery products and/or other ingredients capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms when stored at temperatures in excess of 45 degrees F, if a cold food, or below 140 degrees F, if a hot food. Also included as potentially hazardous food, are low acid canned foods (vegetables, fish, meat, etc.) and acidified foods (pickled vegetables, fish, meat, eggs, etc.).
- **Time/temperature control for safety (TCS) foods** — This category was previously described as "potentially hazardous foods" but that term has been replaced in most regulations by TCS foods. TCS food as defined in the 2013 Food Code means a food that requires time and/or temperature control for safety (TCS) to limit pathogen growth or toxin formation. Time and temperature conditions are similar to those above.
- **Formulated acid foods** — Formulated acid foods contain normally acidic ingredients (pH less than or equal to 4.6) but can have a small amount (less than 10 percent by weight) of low-acid ingredients (pH greater than 4.6) which do not significantly change the pH of the acid ingredients. Final product pH must be equal to or less than 4.6 by definition.
- **Acidified foods** — Low-acid foods to which acid(s) or acid food(s) are added. They have a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below. Acidified foods are intended to be shelf-stable but sometimes need refrigeration after opening to prevent spoilage.
- **Commercial food facility** – A commercial food facility (sometimes referred to as a commercial kitchen) is a commercially-licensed space designed to meet Good Manufacturing Practices regulations for the safe manufacture, processing, packing or holding of foods. Commercial kitchens are typically used for preparing foods for sale and may include shared-use kitchens or incubator kitchens, also sometimes called community kitchens. Commercial kitchens are also used for preparing food that will be consumed on-site, such as at restaurants, hotels, schools, churches, etc.

## Food Regulations Decision Tree

Producers may answer questions posed in this chart to help them identify whether a food manufacturing permit and commercial facility are required for the product they plan to produce and market or whether their plans will require a food service permit from their local health department.

Photo Credit: Tennessee Department of Agriculture

**Is your product packaged for retail or wholesale sale and off-site consumption?**

- **No** → **Non-packaged food prepared for on-site consumption such as for restaurants, concessions and catering is considered food service.**

  **Food service is regulated by the Tennessee Department of Health and/or your local health department.**

  www.tn.gov/health/health-program-areas/eh.html

- **Yes** → **Is your product non-potentially hazardous? (See pages 2 and 6.)**
  - **No** → **A TDA food manufacturing permit is required and food must be manufactured in an inspected commercial facility. Additional training and FDA approval may also be required.**
  - **Yes** → **Are you ONLY selling directly to end consumers (retail sales) within Tennessee?**
    - **No** → **A TDA food manufacturing permit is required and food must be manufactured in an inspected commercial facility. Additional training and FDA approval may also be required.**
    - **Yes** → **Do you have any full-time employees? Or do you include any health claims on the product label?**
      - **Yes** → **A TDA food manufacturing permit is required and food must be manufactured in an inspected commercial facility. Additional training and FDA approval may also be required.**
      - **No** → **No food manufacturing permit is needed.**

        **Products must be made using current Food Manufacturing Practices (cGMPs) and may be made in a noninspected facility/kitchen, including a home or domestic kitchen.**

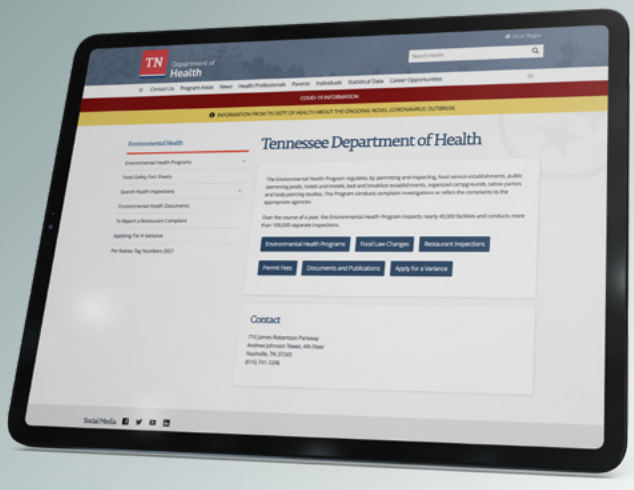
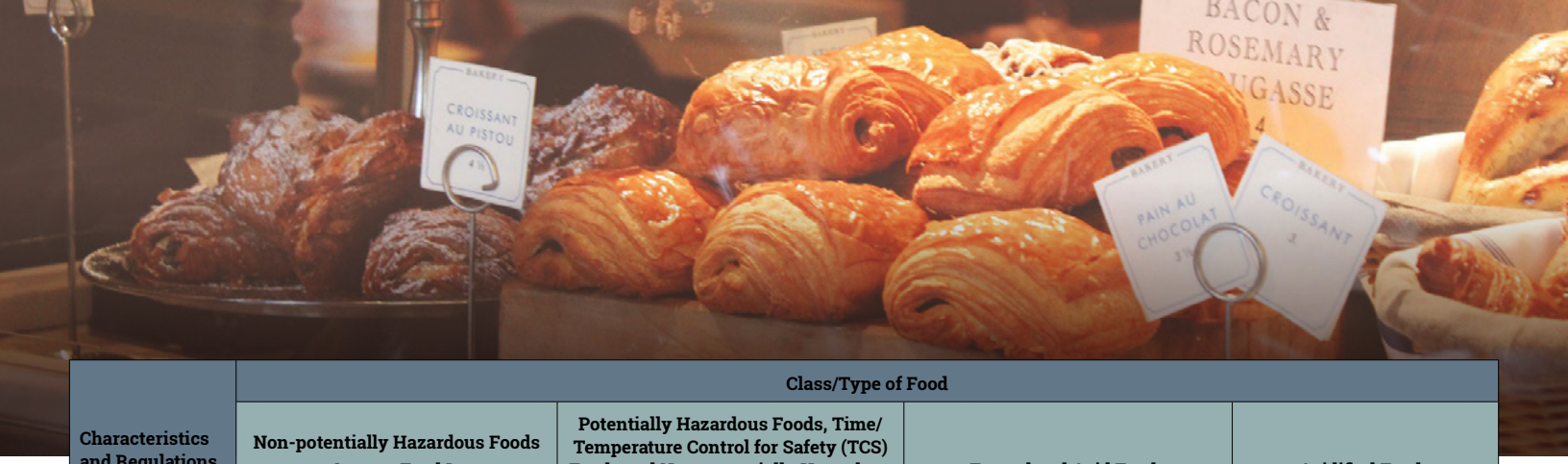


Photo Credit: Tennessee Department of Agriculture

## Summary of Food Manufacturing Regulations in Tennessee by Category of Food

Producers may use the table below to help identify which category of food they plan to manufacture and learn basic information about the regulations involved in manufacturing each type of product.

| Characteristics and Regulations | Class/Type of Food | | | |
|---|---|---|---|---|
| | **Non-potentially Hazardous Foods — Cottage Food Law** | **Potentially Hazardous Foods, Time/Temperature Control for Safety (TCS) Foods and Non-potentially Hazardous Foods Not Covered by Cottage Food Law** | **Formulated Acid Foods** | **Acidified Foods** |
| Common Examples | Baked goods that have a water activity level of less than 0.85; fruit jams, jellies and preserves; fruit butters (apple, peach, etc.); canned fruit (naturally acidic fruits only), candy, dry spices (oregano, thyme, rosemary, sage).<br>Note that recipe modifications such as "low sugar" or adding vegetables (squash, carrots, onions, peppers) may turn a non-potentially hazardous food into a potentially hazardous product. | Baked goods requiring refrigeration (cheesecake, custard or cream pies, etc.); fresh salsas, soups or dips requiring refrigeration; frozen fruit or vegetables; processed or cut fruits and vegetables such as salads; juices; cooked rice and pasta; sandwiches; etc.<br>Non-potentially hazardous products not meeting the limitations of the cottage food law must adhere to this category of regulations as well. | Many shelf-stable sauces and dressings (barbecue sauce, hot sauces, mayonnaise, marinades); canned tomatoes (pH < 4.7); fermented products (kombucha, sauerkraut); sugar-free jams/jellies/apple butters; etc. | Shelf-stable elderberry syrup, salsas, chow-chows, corn relishes, pickles, pickled eggs or vegetables, and some barbecue sauces and hot sauces containing a significant amount of low-acid foods such as peppers. Typically vinegar (acetic acid) or citric acid is used to lower the pH of the product. |
| Definition/ Description | Non-potentially hazardous foods do not support the growth of bacteria, and the processing steps do not require stringent time and/or temperature controls to assure a safe product. Non-potentially hazardous foods are typically naturally acidic (typically pH < 4.2), have a low water activity (Aw < 0.85), or a combination of both that limits pathogen growth.<br>Things high in sugar or salt content, baked, or dried typically have low water activity, but it depends on the actual ingredients and process conditions. | Potentially hazardous food containing ingredients capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms when stored at temperatures in excess of 45 degrees F, if a cold food, or below 140 degrees F, if a hot food.<br>Time/temperature control for safety food means a food that requires time or temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.<br>These foods require time and/or temperature control because they create risks for foodborne illness if not processed, prepared, or handled correctly.<br>Regulations in this column also apply to non-potentially hazardous foods sold wholesale (to a retail store, restaurant, distributor, etc.), sold across state lines, with full-time employees or with health claims on the label. | Acidic foods are lower risk, potentially hazardous foods because most harmful bacterial will not survive or grow under the acidic conditions. Formulated acid foods are normally acid foods (or a mixture of acidic ingredients) but may have a "small amount" of low-acid ingredients added. Regulations require formulated acid foods to have a final equilibrium pH of 4.6 or below. The foods should not contain greater than 10 percent by weight of low-acid ingredients. Also, the low-acid ingredients cannot significantly raise the equilibrium pH of the predominant acid or acidic ingredient(s).<br>pH is a measurement taken with a pH meter that describes how alkaline or acidic a substance is. The pH scale ranges from 0 (the most acid) to 14 (the most alkaline), with 7 considered neutral. Most foods have pH values in the acid range between 2 to 6.5. Whole foods or ingredients are categorized as acid (pH < 4.6) or low-acid (pH between 4.6 and 7.0) based on the natural acidity of the product. | Acidified foods are low-acid foods to which acid(s) or acid food(s) are added to produce a product that has a finished equilibrium pH of 4.6 or below and a water activity greater than 0.85. Equilibrium pH is the condition achieved when all components of the food, both liquid and solid, reach the same pH.<br>For acidified foods, pH control is critical to prevent botulism from the microorganism, clostridium botulinum. |




| Characteristics and Regulations | Class/Type of Food | | | |
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| | **Non-potentially Hazardous Foods — Cottage Food Law** | **Potentially Hazardous Foods, Time/ Temperature Control for Safety (TCS) Foods and Non-potentially Hazardous Foods Not Covered by Cottage Food Law** | **Formulated Acid Foods** | **Acidified Foods** |
| Limitations/ Restrictions | There are several limitations or restrictions for selling non-potentially hazardous foods under the cottage food law. Products must only be sold directly to end consumers (retail sales) within the state of Tennessee. The manufacturer may not have any full-time employees manufacturing foods. The food label cannot include any health claims.<br>Operations selling wholesale (to restaurants or grocery stores, gift shops, etc.), makings sales across state lines, or operating with full-time employees must use a commercial facility and obtain a food manufacturing permit from the Tennessee Department of Agriculture. Refer to column for Potentially-Hazardous Foods, Time/ Temperature Control for Safety Foods and Non-potentially Hazardous Foods Not Covered by Cottage Food Law. | None | None | None |
| Agency(ies) Regulating | Tennessee Department of Agriculture (TDA) | TDA, FDA and/or USDA depending on type of product. | TDA. FDA is also involved if the product will be sold across state lines. | TDA and either FDA or USDA depending on product ingredients. |
| Regulations | Current Good Manufacturing Practices (cGMPs) found in 21CFR part 117 Subpart B.<br>www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements | Current Good Manufacturing Practices. (cGMPs) found in 21CFR part 117 Subpart B and any regulations specific to the product, i.e., HACCP for juices. Facility registration and filing for low acid canned foods (LACF).<br>www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements | Current Good Manufacturing Practices. (cGMPs) found in 21CFR part 117 Subpart B.<br>www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements | Current Good Manufacturing Practices. (cGMPs) found in 21CFR part 117 Subpart B and Acidified Foods Regulations 21 CFR parts 108 & 114.<br>www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements |
| Facility Requirements | Non-potentially hazardous foods meeting the cottage food requirements may be manufactured in a home or other non-inspected facility or kitchen. Products not meeting the limitations described above must be manufactured in a commercial facility. | Commercial facility. Work with TDA's Consumer and Industry Services Division to review and approve any remodeling or new construction plans. | Commercial facility. Work with TDA's Consumer and Industry Services Division to review and approve any remodeling or new construction plans. | Commercial facility. Must register facility location with the FDA using Form 2541 — www.fda.gov/media/72055/download. Work with TDA's Consumer and Industry Services Division to review and approve any remodeling or new construction plans. |

| Characteristics and Regulations | Class/Type of Food | | | |
|---|---|---|---|---|
| | **Non-potentially Hazardous Foods — Cottage Food Law** | **Potentially Hazardous Foods, Time/ Temperature Control for Safety (TCS) Foods and Non-potentially Hazardous Foods Not Covered by Cottage Food Law** | **Formulated Acid Foods** | **Acidified Foods** |
| Education/ Certification(s) Required | None | None | None | Better Process Control School for Acidified Foods — foodscience.tennessee.edu/better-process-control-school-course |
| FDA Scheduled Process Required | No | No | No, however, manufacturers are encouraged to work with a food safety expert or "process authority," to develop a manufacturing process and determine any critical factors for their product. | Yes — 1) Work with processing authority to establish a scheduled process for each product. 2) File the scheduled process with FDA using Form 2541e for each product in each container size. www.fda.gov/food/establishment-registration-process-filing-acidified-and-low-acid-canned-foods-lacf/establishment-registration-process-filing-acidified-and-low-acid-canned-foods-lacf-paper-submissions |
| FDA Registration in Compliance with Bioterrorism Act | None | The Public Health Security and Bioterrorism Preparedness Response Act of 2002 also requires food manufacturing facilities to register with the FDA. This registration is separate from Form 2541 and may be completed online at www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions. | | |
| TDA Permit(s) Required | None | TDA Commercial Food Manufacturer Permit | | |
| Additional Requirements | | | | Keep accurate records documenting all critical factors for each batch process (e.g., cook time, temperature, finished product pH, fill weights, solid fill weight, etc.). |
| Labeling Requirements | Required label components: 1. Common or usual name of product 2. Manufacturer's name and address 3. Net weight of product in English and Metric Units 4. Complete list of ingredients in order of predominance by weight (including allergens by name such as wheat, soy, milk, eggs, fish, shellfish, peanuts, tree nuts) 5. Lot dates or code for traceability in event of a food safety issue requiring a recall 6. Facility registration number (for USDA products and acidified products) 7. UPC code if required by retailer. | | | |
| Nutrition Facts Panel | Not required under Small Business Exemption for businesses with sales of less than 100,000 units, less than 100 employees and no nutrition claims (e.g., low fat, sugar free). Businesses must file notice of Small Business Exemption with FDA unless 1) does not import 2) sales of less than 10,000 units 3) less than 10 full-time employees. Some wholesale buyers may require nutrition facts panels. Larger manufacturers are required to have nutrition facts panel. | | | |
| Additional Resource | PB 1881 Manufacturing Non-potentially Hazardous Foods for Sale in Tennessee Without a Permit extension.tennessee.edu/publications/Documents/PB1881.pdf | | SP 747-B Manufacturing Formulated Acid Foods in Tennessee, extension.tennessee.edu/publications/Documents/SP747-B.pdf | SP 747-A Manufacturing Acidified Foods in Tennessee, extension.tennessee.edu/publications/Documents/SP747-A.pdf |


Photo Credit: Franklin Farmers Market


## Additional Resources

Contacts or links to additional resources for potential food manufacturers are provided in this section.

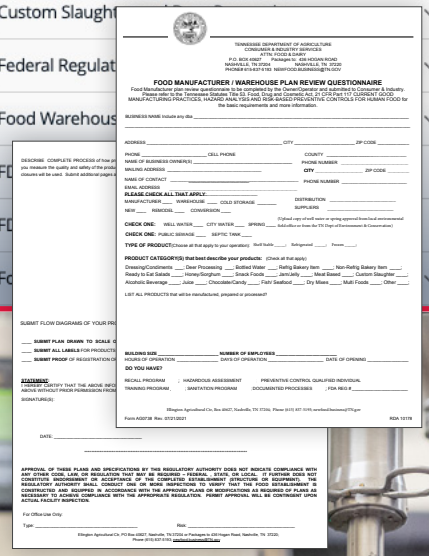
### Still need help identifying a food product category?

Some manufacturers may need some extra help in identifying the regulations involved, and sometimes the category of regulation for a food may depend on a specific recipe. Producers should feel free to contact the Tennessee Department of Agriculture, Consumer and Industry Services for additional guidance at 615-837-5193. The University of Tennessee's Department of Food Science can also assist with identifying regulatory status of a particular product. The university can also test product pH and water activity to assist in this determination, for a small fee. You can request assistance by emailing: Foodsci_ext@utk.edu or visiting foodscience.tennessee.edu/food-science-extension.

### Working with a Processing Authority

The regulations for acidified foods state that manufacturers must work with a process authority to determine an appropriate scheduled process for each product. This person has the training and experience necessary to determine the appropriate processing conditions and critical factors needed to produce a commercially sterile product as required by the acidified food regulations. Mark Morgan, a professor and UT Extension specialist, serves as a process authority for acidified foods and will work with manufacturers to evaluate products and processing conditions to determine the appropriate process and any critical factors that are pertinent to produce a wholesome acidified food. Contact him at mark.morgan@tennessee.edu.

Food Manufacturing and Warehousing
TDA Licensed Community Kitchen Operations
Cottage Foods
Custom Slaught
Federal Regulat
Food Warehous



FOOD MANUFACTURER / WAREHOUSE PLAN REVIEW QUESTIONNAIRE

# Starting a Food Manufacturing Business in TN

Whenever a food establishment is constructed, remodeled or whenever an existing structure is converted to use as a food establishment, plans and specifications must be submitted to the Tennessee Department of Agriculture (TDA), Consumer & Industry Services, prior to the start of construction, remodeling or conversion. Construction of the food establishment cannot begin until TDA has completed their review and given their approval.

**What is required of new manufacturers within the State of Tennessee?**

- All manufacturers are required to obtain a license in accordance with Tennessee Food, Drug and Cosmetic Act and Chapter 0080-04-13.

**Where do I get the license to manufacture within the State of Tennessee?**

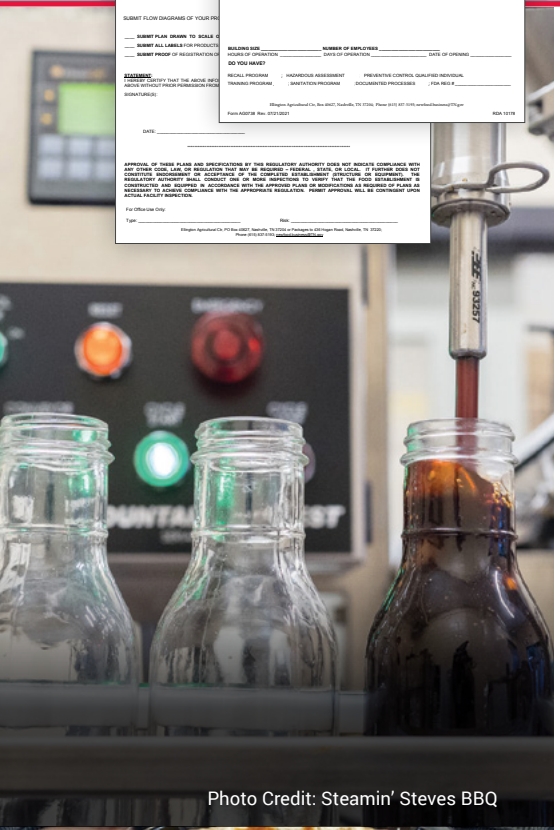


Photo Credit: Steamin' Steves BBQ

Photo Credit: Franklin Farmers Market

## Better Process Control School

Manufacturers of acidified and low-acid canned foods are required to complete a Better Process Control School course. Food manufacturers processing low-acid or acidified foods must operate with a supervisor who has attended Better Process Control School on hand at all times during processing. Many operations will also elect to send individuals integral to processing, container evaluations, and sanitation to the course as well. The UT Department of Food Science offers in-person and online courses. Learn more at foodscience.tennessee.edu/better-process-control-school-course.

## How to Start the Food Manufacturing Permit Process with the Tennessee Department of Agriculture

Once ready to start the food manufacturing permit process with the Tennessee Department of Agriculture, contact TDA's Food Manufacturing Outreach Coordinator at 615-837-5193 and/or complete the TDA Food Manufacturer/ Warehouse Plan Review Questionnaire at www.tn.gov/content/dam/tn/agriculture/documents/foodsafety/Food_Manufacturing_Warehouse_Plan_Fillable.pdf.

Learn more about what is needed to obtain a TDA food manufacturing license at www.tn.gov/agriculture/consumers/food-safety/ag-farms-food-manufacturing-and-warehousing/startup.html.

## Helpful Links

Find additional resources for producers and entrepreneurs interested in food manufacturing at:

- Tennessee Department of Agriculture Consumer and Industry Services — Food Safety: www.tn.gov/agriculture/consumers/food-safety.html
- UT Extension Center for Profitable Agriculture: cpa.tennessee.edu
- UT Extension Department of Food Science: foodscience.tennessee.edu/food-science-extension

Photo Credit: Franklin Farmers Market

## Summary

Regulations often seem overwhelming to potential entrepreneurs and industry partners. Identifying which regulations apply to a manufactured food product and which regulatory agencies are involved are some of the first major steps in analyzing, planning and developing a new business. This fact sheet summarizes Tennessee food manufacturing regulations by food category to help farmers and potential food manufacturers and industry partners begin to understand requirements for manufacturing and marketing manufactured foods.


Photo Credit: Tennessee Department of Agriculture

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