



Getting Started **in a** Food Manufacturing Business **in** Tennessee

Third Edition

THE UNIVERSITY of TENNESSEE **UT**
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Getting Started in a Food Manufacturing Business in Tennessee

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If you enjoy cooking and have an interest in developing your own business, you may be interested in making a food product and selling it to the public. Friends may have complimented the foods you have prepared, or you have some unique foods or ingredients that, if manufactured and marketed properly, could enable you to begin a business venture.

Like any small business, food enterprises require careful planning, dedication and skilled management to be successful. The food business is unique when compared to most other types of businesses, as you are involved in a venture that can have a direct effect on your customers' health and safety. You must comply with a number of complex and often confusing federal, state and local regulations when making and selling food products. Competition is intense in the food business. It is extremely difficult to have a product accepted by a major grocery chain or nationwide food establishments. Owning your own business can be very exciting. It also requires a lot of hard work and commitment, is very time-consuming, and technical knowledge of foods is a necessity. The words "foodborne illness" should send a shiver down the spine of anyone who operates a food business. Whether caused by *E. coli* 0157, *Listeria*, *Salmonella*, botulism or any number of other disease-producing microorganisms, foodborne illness can destroy a successful business in a matter of hours.

"Keep hot foods hot and cold foods cold" is a good rule of thumb for food safety. Do not serve any foods that have not been kept at their recommended cold or hot temperature ranges until serving time. Most

bacteria that cause illness thrive in the range between 40 degrees and 135 degrees Fahrenheit. Once hot foods have cooled to a temperature that's within this range, they need to be reheated above 165 degrees F. Refrigeration will slow the growth of bacteria, but it will not kill them. Potentially hazardous foods include those that contain meat, fish, poultry, eggs and milk products. Proper holding temperatures are especially important for these products.

This publication outlines the steps and ideas you need to consider before starting a food or food-ingredient business. It is written for food manufacturing businesses and does not address the general feasibility considerations that concern all businesses (i.e., production practices, finances, markets, location, competitors, daily management, etc.). As a potential business entrepreneur, you should strongly examine the feasibility of the business, in addition to the specific points covered in this publication.

I. Should You Start Your Own Business?

Volumes of literature have been written on this subject, but two excellent synopses to evaluate yourself and your situation include publication PB1754, *Agrotourism in Focus: A Guide for Tennessee Farmers*, with special emphasis on Chapter 3: Business Planning, published by University of Tennessee Extension, and the *Tennessee Small Business Guide*, published by the Tennessee Department of Economic and Community Development.

There are many steps between a “great idea” and scaling it up to a successful business. The following nine steps will lead you through a logical thought process so you may progress in a well-planned manner.

1. Evaluate your personal characteristics.
2. Develop a business idea.
3. Write a business plan.
4. Translate the idea into distinct consumer benefits.
5. Evaluate the competition.
6. Redefine and improve your idea.
7. Examine market conditions.
8. Design the smallest possible viable business unit.
9. Act on your idea.

II. The Legal Aspects

The food industry has special considerations in addition to the factors

of concern to every business. Knowing the regulations governing food and the facilities in the production, processing, storage and dispensing of a product is an absolute necessity. Knowing them also is the legal responsibility of the owner of any business.

In the planning stages, initially you should check the local zoning ordinances to determine if the particular business activity may be carried out in the chosen geographic location. Local zoning regulations may restrict the kinds of home businesses allowed or prohibit home food businesses entirely. If zoning laws are confusing to you, or if you have any questions about them, ask local officials to clarify the rules. Do not make any plans until you are satisfied that your business will fall within the bounds of the current laws. If you plan a business with the idea that you will get local zoning ordinances and laws changed, you may be in for an unpleasant surprise. Renting or constructing a suitable facility may be required.

The Tennessee Department of Agriculture (TDA) is responsible for regulating and enforcing food safety as it pertains to food processing, handling, storage and sale in Tennessee. All foods prepared at any location, including the home, for sale to consumers, distribution or retailers fall under the responsibility of both TDA and the local county health department. A catering business operated from the home must be approved and regulated by the Tennessee Department of Health (TDH). To be sure you are familiar with all the required regulations, read and understand the Tennessee Food, Drug and Cosmetic Act, Good Manufacturing Practices (GMPs) in Appendix A and the packaging and labeling regulations in Appendix B. Other policies, including the weights and measures laws issued by the Tennessee Department of Agriculture, should be understood and complied with. A copy of these can be obtained from the Division of Regulatory Services, Food and Dairy Section, Tennessee Department of Agriculture, P.O. Box 40627, Melrose Station, Nashville, TN 37204, phone: 615-837-5193.

Tennessee regulations state specifically that food prepared on home premises must meet the same requirements as any commercial food manufacturing plant. No operations of a food service establishment (or retail food store) shall be conducted in any room used as living or sleeping quarters, such as the home kitchen. The only exception to this regulation is the production of nonpotentially hazardous foods, which

are discussed in further detail in the following section. For all other food products that are considered potentially hazardous, a separate kitchen that is closed off from the rest of the home by a solid door must be provided.

The equipment that may be used also is controlled. For example, your old favorite wooden mixing spoon is not permissible. In addition, a product sold across state lines will become subject to regulations of the Federal Food, Drug and Cosmetic Act and Fair Packaging and Labeling Act. These include labeling, ingredients, preparation and handling requirements. The Good Manufacturing Practices (GMP) set for your manufacturing facility by the TDA are the same as required by the FDA.

The TDA Regulatory Services Division must inspect your premises and issue you a copy of the approved “Inspection Report” before you are authorized to manufacture or process food. (See Appendix C for sample form.) This procedure is applicable to any food wholesaler, manufacturer or processor, except for the following types of food:

- a. Meat products or products containing meat ingredients (must be processed in a United States Department of Agriculture [USDA] approved/inspected facility).
- b. Low-acid (pH 4.6 and above) and acidified canned foods.

All commercial processors of heat-processed “low-acid” canned foods and acidified foods are required to register their establishments and submit processing information for all such products with the Food and Drug Administration on appropriate forms. Full text of the low-acid canned food and acidified food regulations is in the Code of Federal Regulations, Title 21, Parts 108, 113 and 114. These regulations may be obtained from the Food and Drug Administration, Industry Guidance Branch (HFF-326), 200 C. St. SW, Washington, D.C. 20204.

Remember, no person can legally operate a food service or processing facility without proper approval from the Tennessee Department of Agriculture, Tennessee Department of Health or USDA.

Preparation of Nonpotentially Hazardous Foods in a Domestic Kitchen

All foods made in the domestic kitchen must be defined as “nonpotentially hazardous foods” (see Chapter 0080-4-11, Regulations for Establishments Utilizing Domestic Kitchen Facilities for Bakery and Other Nonpotentially Hazardous Foods Intended for Sale). Individuals preparing nonpotentially hazardous foods in a domestic kitchen are encouraged to have their kitchen inspected and permitted by the Tennessee Department of Agriculture Regulatory Services Division. However, these individuals may elect to opt out of inspection and permitting.

Those individuals who elect to forgo inspection and permitting must meet certain stipulations. The nonpotentially hazardous foods are limited to direct market sales at their residence, community social events, flea markets and farmers markets located in the state. They must display an 8 ½” x 11” sign with a ¾” font at the place of sale, stating: “These food products were made in a private home not licensed or inspected.” This statement must also appear on the product label. Other stipulations, such as adherence to good manufacturing practices and product labeling requirements, also must be adhered to.

Domestic kitchen manufacturers may choose to have their kitchens inspected and permitted by the Tennessee Department of Agriculture Regulatory Services Division for several reasons. Although not required by law, farmers market managers may stipulate that all market vendors be inspected and permitted or if you would prefer not to display the signage described above you would need to be inspected and permitted. In addition, any nonpotentially hazardous product intended for sale not direct to consumer must be manufactured in an inspected and permitted domestic kitchen. If electing to undergo inspection and permitting, your facility and practices would need to meet all the requirements outlined in Chapter 0080-4-11, Regulations for Establishments Utilizing Domestic Kitchen Facilities for Bakery and Other Nonpotentially Hazardous Foods Intended for Sale. These requirements are somewhat forgiving for floors, walls and ceilings when complying with Good Manufacturing Practices (GMPs) 21CFR Part 110. For example, in the domestic kitchen, clean carpeting and curtains are allowed, whereas in a commercial kitchen, they are not allowed. In the domestic kitchen, an adjacent bathroom can serve as the

handwashing station. Also, the normal two-compartment sink suffices for cleaning and sanitizing utensils and equipment, whereas a three-compartment sink is required for commercial food manufacturers.

Participation in a one-time food safety training for all domestic kitchen manufacturers undergoing inspection and permitting also is required. However, participation in this training is highly encouraged for all domestic kitchen manufacturers. This knowledge can be pertinent for individuals who are new to manufacturing food to educate them on the tenets of food microbiology and how to safely manufacture foods. Topics covered include an introduction to food microbiology, GMPs, cleaning and sanitation, allergens, and product labeling. This training is offered by the University of Tennessee Department of Food Science and Technology in classes taught throughout the state as well as online. For more information, please contact the Food Science Department at 865-974-7717.

It also is important to understand that “acidified foods” (pickled vegetables, salsas) or “formulated acid foods” (marinades, hot sauces, salad dressings, etc.) are not considered nonpotentially hazardous and cannot be manufactured in a domestic kitchen under any circumstances. These products must be manufactured in a commercial kitchen.

Manufacturing Acidified Foods

Acidified foods are foods with a natural pH above 4.6 that are processed with acidified agents such as vinegar to decrease the pH below 4.6 to help create a shelf stable product. If you wish to manufacture an acidified food, you must meet several requirements. In addition to manufacturing in a commercial kitchen that is inspected and permitted by the Tennessee Department of Agriculture, you must have registered your facility (form 2541) and filed a process for each product (form 2541a) with the U.S. Food and Drug Administration (FDA) and be compliant with 21CFR part 114. In order to establish an adequate process, you will work with a processing authority that will review pertinent data such as your product formulation, processing parameters and finished product equilibrated pH. You also will need to successfully complete a Better Process Control School that will cover many topics that manufacturers of acidified foods will be responsible for understanding and implementing while manufacturing their products.

Inspection Report

Before your facility is constructed or remodeled, or if an existing structure is converted to use as a food manufacturing facility, a prepared set of plans and specifications (blueprints) of such construction, remodeling or conversion must be submitted to the TDA for review and approval.

Upon the state's approval of these plans, construction may begin and be completed. If changes are made in the originally approved plans, they must be approved by the same office. However, you may not begin the operation of your business until the state has inspected your facility and determined that you have complied with the approved plans and specifications. Only at this time will you be granted the permit to operate your business. For USDA meat plants, the approval must be obtained from USDA Food Safety Inspection Service (FCIS).

In the early stages of your business, it is wise to use the many resources that are available to you. The Tennessee Small Business Development Center (TSBDC) serves as a focal point for the coordination of federal, state, local, university and private resources to aid small businesses. These services are delivered through regional and affiliate centers located at state universities, community colleges and technical institutes. Contact the office nearest you for assistance in various business areas such as writing business plans or seeking answers for financial assistance. A list of these offices with their addresses and telephone numbers is in Appendix E. The Tennessee Department of Agriculture Division of Marketing is a resource available to new and existing businesses to assist in marketing their products (see Appendix D). The marketing division can include your business in their resource directory and can assist in displaying your products at trade shows.

One of the first steps is to contact your county clerk's office to obtain an appropriate business license. This license is required for tax purposes. Another important step is to contact TDA or TDH for the appropriate state food permit. The type of food business you are starting will determine which of the three state permits will be required.

III. Types of Permits Issued in Tennessee

Three types of permits are issued in Tennessee, depending on the type of food business you are involved in. Listed below are the three categories. Contact the appropriate governmental agencies while you are in the early stages of your planning.

1. Retail Food Store Permit — Issued by TDA; it covers all grocery stores and any restaurants in these grocery stores. It also covers any establishment where food and food products are offered to the consumer and intended for off-premise consumption. Example: Bakeries that sell both at the retail and wholesale level are regulated by TDA, whereas, bakeries selling only at the retail level are covered by the Tennessee Department of Health, Division of General Environmental Health, Cordell Hull Bldg., 425 Fifth Ave. N., Nashville, TN 37247, phone: 615-741-7206.
2. Food Service Establishment Permit — Issued by the Tennessee Department of Health. It covers all restaurants.
3. Wholesale and Manufacturing Processing Plants — These are regulated by the TDA, but there is a “permit” issued. They are issued a copy of the TDA Regulator Services, Food and Dairy Section’s “Food Establishment Inspection” form before the process is started (see Appendix C). A fee is charged based on the size of the operation.
4. Domestic kitchen permit (only for nonpotentially hazardous foods).

The following list summarizes some of the key issues involving the Tennessee Department of Agriculture food inspection program:

- a. The Department of Agriculture inspects retail food stores (groceries, markets, delis, etc.)
- b. The Health Department inspects food service establishments (restaurants, schools, daycare facilities, hospitals, etc.)
- c. There are approximately 8,100 retail food stores in Tennessee.
- d. The Retail Food Store Law requires that each establishment is inspected at least once every six months and as often as deemed necessary.

- e. The Department of Agriculture contracts inspection in Davidson, Knox and Shelby counties.
- f. All consumer complaints regarding retail groceries wholesale, manufacturing and processing facilities and convenience stores go to TDA (615-837-5193); all restaurant complaints are directed to the local county health department.
- g. Food samples are routinely picked up and checked for, among others: *E. coli* 0157:H7, *Listeria*, fat content, species identification, aflatoxin and pesticide residue.
- h. All retail food stores are required by law to have a permit inspection report available for public disclosure to any person who requests to review it.
- i. The department has the authority to levy civil fines against establishments with repeat violations. These penalties can be up to \$500 per violation.
- j. Stores are scored on a 44-item checklist, for a total of 100 points. Items are weighted 1, 2, 4 and 5 points — with the 13 4- and 5-point items being considered critical. These critical items must be corrected as soon as possible, and in any event within 10 days following an inspection. Follow-up inspections may be made for confirmation. A score below 70 requires a follow-up inspection.
- k. Permits to operate also may be suspended or revoked after due process.
- l. Immediate closure of all or part of an establishment is required if an imminent health hazard exists.
- m. All new stores are required to submit plans for approval before construction and also for extensive remodeling.
- n. The Tennessee Department of Agriculture also inspects hundreds of food manufacturers, food warehouses, bottled water, wineries, bakeries, etc. These include small one- and

two-person operations up to the largest food manufacturers in Tennessee.

- o. The U.S. Department of Agriculture inspects meat and poultry processing plants.
- p. The Tennessee Department of Agriculture does contract inspections for the U.S. Food and Drug Administration.

IV. Effluent and Waste Water

In most food-processing facilities, a certain amount of waste is generated. This can be in dry, semi dry or liquid form. Whatever the state of your waste, it can be a serious problem if proper plans for its disposal are not considered in the planning and construction phases of your facilities.

Food-processing wastes can be a substantial ecological hazard to our environment. It also is against state and local laws to discharge any biological waste into public waterways or into a local sanitary sewer without proper permits. These permits are usually based on the BOD (Biological Oxygen Demand) and suspended solids content if the waste is liquid and is being discharged into a local sanitary sewer system. In many cases, if your waste is solid, you may need to pay a solid waste disposal company for its removal. The waste from some processes is of value, and it may be sold to another processor or producer.

For guidance on proper handling of specific process wastes, contact your local county health department.

V. Good Manufacturing Practices (GMPs)

For a complete description of GMPs, see Appendix A.

Subpart A—General Provisions

§ 110.3 Definitions.

§ 110.5 Current good manufacturing practice.

§ 110.10 Personnel.

§ 110.19 Exclusions.

Subpart B—Buildings and Facilities

- § 110.20 Plant and grounds.
- § 110.35 Sanitary operations.
- § 110.37 Sanitary facilities and controls.

Subpart C—Equipment

- § 110.40 Equipment and utensils.

Subpart D [Reserved]

Subpart E—Production and Process Controls

- § 110.80 Processes and controls.
- § 110.93 Warehousing and distribution.

Subpart F [Reserved]

Subpart G—Defect Action Levels

- § 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

Part of the Good Manufacturing Practices for all food plants is reprinted in Appendix A; for additional information, see the Code of Federal Regulations, CFR 21, parts 100-169.

Remember, as you develop plans for your food processing facility, the Tennessee Department of Agriculture, Regulatory Services, Food and Dairy Section, requires a review of these plans.

Listed below is the basis of their review and the key points to be addressed in your new or remodeled facility:

1. Walls, floors and ceilings in food preparation, handling, storage, warewashing areas and toilet rooms must be light-colored, smooth, nonabsorbent and easily cleanable. (If concrete floors are used, they must be sealed.)
2. All fixed equipment must be sealed to the wall, unless sufficient space is provided for easy cleaning between, behind and above each unit.

3. All wiring and plumbing must be installed in a way that does not obstruct or prevent cleaning (behind wall).
4. Floor-mounted equipment, unless easily moveable, shall be sealed to the floor, or elevated to provide at least a 6-inch clearance between the floor and equipment.
5. Lights located over food preparation and food display facilities and warewashing areas must be shielded, coated or otherwise shatter-resistant.
6. Restrooms must be properly ventilated.
7. Condensation drain lines must be air-gapped going into the sewer system.
8. All threaded faucets must have a backflow preventer installed.
9. All outer doors and restroom doors must have self-closures.
10. A conveniently located handwash sink must be provided in each food preparation and warewashing area. Handwashing facilities also shall be located in or immediately adjacent to toilet rooms or their vestibules.
11. Grease traps, if used, shall be located to be easily accessible for cleaning.
12. Except for properly trapped open sinks, there shall be no direct connection between the sewerage system and any drains originating from equipment in which food, equipment or utensils are placed.
13. An adequate and effective hood and exhaust system must be provided over all deep fat fryers, broilers, griddles, ranges, steam cookers and similar equipment that produce comparable amounts of steam, smoke, grease or heat; systems shall be installed and operated according to applicable laws.

14. Dumpsters and outside storage areas must be located on smooth, nonabsorbent surfaces.
15. All food that may come into contact with the public during display or storage must be protected by an adequate and effective sneeze guard.
16. Ice shall not be provided for self-service unless served through a sanitary ice dispenser.
17. Potable water sufficient to meet all needs shall be provided from a source approved by the Tennessee Department of Environment.
18. All sewage, including liquid waste, shall be disposed of by a public sewerage system or by a sewage disposal system approved by the Tennessee Department of Health.
19. Warewashing sinks with two or three compartments shall be provided and used according to retail food store regulations. These compartments shall be large enough to accommodate the immersion of equipment and utensils, and each compartment shall be supplied with hot and cold potable running water. Handwashing is prohibited in warewashing sinks.
20. Refrigerated, frozen and hot storage units shall be provided in such manner and of such capacity to assure the maintenance of potentially hazardous food at the required temperature during storage and display.
21. Equipment, including ice makers and ice storage equipment, shall not be located under exposed or unprotected sewer lines, water lines that are leaking or on which condensed water has accumulated, open stairwells or other sources of contamination.
22. At least one service sink or curbed cleaning facility with a floor drain shall be provided for the cleaning of mops and for the disposal of mop water or similar liquid wastes.

VI. Weights and Measures

Let us now direct our attention to proper net weights in English and metric units and computation of tares. Tare is the weight of a container or wrapper that is deducted from the gross weight to obtain net weight. State law defines net weight as the exact weight of a commodity in a package at the time it is offered for sale. Net weight must allow for product shrinkage. In other words, the law requires that the commodity itself must weigh at least as much as the label declaration at the time it is offered for sale. Colder temperatures during processing, packaging and display will reduce product shrinkage, extend shelf life and achieve maximum profits.

VII. Product Labeling

All food and nonfood items packaged by your business must be properly labeled prior to sale. The law requires the following to be on all food items:

1. The name, street address, city, state and ZIP code of either the manufacturer, packer or distributor.
2. An accurate statement of the net amount of food in the package in English and metric units.
3. The common or usual name of the food.
4. The ingredients in the food, listed in order of predominance by weight. For further details, see Appendix B and/or FDA Regulations (21 CFR 101).

After you have designed and written your label, it is highly recommended that you submit it for review and comments to the Regulatory Services, Food & Dairy Section, Tennessee Department of Agriculture. This step is not required by law; however, this is a service provided by this office, and it can save you time and money. Any food product that makes a nutritional claim or adds nutrients must comply with Nutritional Labeling (see Code of Federal Regulations [21CFR 101.9]).

VIII. UPC (Universal Product Code)

If you wish to sell your product in retail grocery chain stores, it is best to obtain a UPC code. This code is a series of barcodes that allows your

product to be checked out at grocery stores' automated cash registers. There is a minimum fee of \$760 to obtain up to 100 barcodes and an annual renewal fee.

To obtain a UPC code for your product, contact the following office for the appropriate application:

GS1

7887 Washington Village Drive, Suite 300

Dayton, OH 45459

Phone: 937-435-3870

Fax: 937-435-7317

Or, you may start the process online at <http://www.gs1us.org>.

IX. Insurance

Insurance helps safeguard your business against losses that result from events such as fire, illness and injury. When you purchase an insurance policy, generally you shift at least a portion of the financial risk of certain losses to an insurance company. Liability insurance refers to coverage for injury to another person or damage to another person's property for which you are legally responsible. Virtually every business should be covered by a liability insurance policy. The alternative to purchasing liability insurance is to "self-insure" for liability losses. Self-insuring involves maintaining sufficient cash reserves to pay for the defense of claims and to pay valid claims. One could argue that the level of these cash reserves might need to be in the hundreds of thousands of dollars. Most businesses choose to purchase a liability insurance policy instead of keeping cash reserves that are adequate to self-insure.

Talk with your insurance agent about your business needs for insurance as you will want to have adequate liability insurance. If you are operating a business in your home, the agent can make sure business use of your home is compatible with your homeowner's policy. In addition to a homeowner's policy that provides personal coverage, you may need a commercial general liability policy that provides additional protection.

The following insurance needs should be considered and reviewed with your insurance agent:

- **Product Liability Coverage** — protects you if your product causes injury to the user or others affected by the use of the product. For example, if you sell food to a restaurant that is infected with a pathogen, you are potentially liable to the restaurant and its customers. Make sure your policy does not exclude product liability coverage for the product you are selling. Many standard policies exclude processed products or products obtained from suppliers. Also, make sure to have coverage that extends beyond the premises where the product is grown or packaged, known as “products-completed operations.”
- **Auto Liability and “Hired Auto and Non-owned Auto” Liability Insurance** — protects you when a vehicle is used in your business, whether it is the owner’s vehicle or employee’s vehicle, to perform a task.
- **Medical Payments Insurance** — provides for payment if someone is injured in your business, whether or not it was your fault.
- **Workers’ Compensation** — covers injuries and occupational diseases that arise from the job and that cause either disability or death. Generally, Tennessee employers with five or more full- or part-time employees at any one time are required to carry workers’ compensation insurance on those employees. In a corporation, the business itself is considered the employer. Owners and corporate officers considered employees are included in the count of total workers, as are family members who are paid.
- **Business Interruption Insurance or Business Income Insurance** — covers the loss of income that a business suffers after an event such as fire or other disaster. This covers the profits that would have been earned while waiting for the facility or equipment to be replaced.
- **Disability Income Protection** — provides short-term and long-term benefits to replace a portion of gross salary if you become disabled.
- **Business Life Insurance** — provides funds to aid the business after the death of a key person in the business.

Be sure to keep all of your insurance records and policies in a safe place — either with your accountant or in a safe deposit box. If you keep them at home for convenience sake, give your policy numbers and insurance company names to your accountant or lawyer or put a list in your safe deposit box.

Perhaps most important is that you should read and understand all the fine print and exclusions in your insurance policies. Re-evaluate your business insurance needs frequently.

X. Financial Assistance

Grants and Foundation Support, Selected Sources of Information, a CRC (Congressional Research Service) Report for Congress, 87-970C, can be obtained by contacting your U.S. representative's office. This publication lists sources and databases that provide information on how and where to get money for projects. The address and telephone number is listed in Appendix D. Most small businesses start with personal investment, loans from family, friends and/or business loans from banks and other commercial sources.

XI. Trademarks

Trademarks are distinctive names or symbols used by a company to distinguish its products from those produced by any other company.

The creation and use of a trademark is the first step in making it exclusively yours. If the trademark is used in interstate commerce, you can register it with the U.S. Patent and Trademark Office. This registration costs \$325-\$375 and gives you the legal rights to the trademark for 10 years; you may renew it every 10 years thereafter.

The book, "Basic Facts About Registering a Trademark," may be useful if you are considering registering your trademark. It and other information may be obtained from:

Assistant Commissioner for Trademarks
South Tower
2900 Crystal Drive, Third Floor
Arlington, VA 22202
Phone: 1-800-786-9919

XII. Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The events of Sept. 11, 2001 created an additional level above food safety — something referred to by food regulators as food security. Guidance documents and laws have been put in place to minimize the risk that food will be subject to tampering or other malicious, criminal

or terrorist actions. A new law places additional requirements on all food producers.

Congress established the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the Bioterrorism Act), which requires domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with the U.S. Food and Drug Administration (FDA). Owners, operators or agents in charge of domestic or foreign facilities are required to register the facility with the FDA. Domestic facilities are required to register with the FDA, whether or not food from the facility enters interstate commerce.

Registration provides the FDA with information on your company, the products you produce, and the name(s) and contact information for responsible persons in your business. There is no fee for registering.

Register online at <http://www.fda.gov> and follow the links to the forms for completing food registration. A system also is in place to register using printed forms that are available from the local FDA office (see Appendix D).

The following firms are exempted from registration: farms; retail food establishments; restaurants; nonprofit establishments that prepare food for, or serve food directly to, consumers; fishing vessels not engaged in processing [as defined in 21 CFR 123.3 (k)]; and facilities regulated exclusively throughout the entire facility by the U.S. Department of Agriculture.

Additional information on food security may be obtained by visiting the FDA website (<http://www.fda.gov>) or requesting copies of food security documents from the local FDA office (see Appendix D).

XIII. Summary

Entrepreneurship is an enviable quality that many individuals have or desire to have. People starting their own food business come from all walks of life. No one should feel unqualified just because they are not familiar with the food business or the technical aspects of food. What you must have, however, is independence, initiative and ideas. These combined with good business sense and the willingness to seek outside help in areas in which you are not knowledgeable will give you a better chance of success.

Anyone considering a new business should be aware that definite risks are involved. Some people find out too late that they do not have the discipline it takes to run a successful business; others may put up a lot of money or quit a good-paying job only to find out too late that there is much more to running a business than what first meets the eye. You should do a self-examination of your personal qualities and have a detailed business plan before you make any permanent commitments.

A multitude of technical resources are at your disposal. It will be your responsibility to use these resources to the best of your ability. Your Extension offices at the state and county level are eager to help you and are available free of charge. Extension specialists may be used as resources in a wide array of areas, from drafting a business plan to technical advice on how to formulate a specific food product. The Departments of Food Science and Technology, Agricultural Economics, Plant Sciences and Biosystems Engineering at the University of Tennessee can all be valuable assets to a beginning food business. Other excellent resources are the TDA, FDA, BCD and TDH. Appendix D gives a more complete list of resources that you will find useful.

Appendix A

Good Manufacturing Practices 21CFR Part 110

110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.
- (b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) *Blanching*, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) *Critical control point* means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) *Food* means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- (g) *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.
- (h) *Lot* means the food produced during a period of time indicated by a specific code.

(i) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective “microbial” instead of using an adjectival phrase containing the word microorganism.

(j) *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) *Plant* means the building, or facility, or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) *Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) *Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

(o) *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) *Shall* is used to state mandatory requirements.

(q) *Should* is used to state recommended or advisory procedures or identify recommended equipment.

(r) *Water activity* (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

- (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
 - (2) Maintaining adequate personal cleanliness.
 - (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
 - (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
 - (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
 - (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
 - (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
 - (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
 - (9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
- (c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of

education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more “raw agricultural commodities,” as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B—Buildings and Facilities

110.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may

be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

110.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.*

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's

guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- (i) Those required to maintain clean and sanitary conditions;
- (ii) Those necessary for use in laboratory testing procedures;
- (iii) Those necessary for plant and equipment maintenance and operation; and
- (iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control.* No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any

interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils.

Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

- (1) Carry sufficient quantities of water to required locations throughout the plant.
 - (2) Properly convey sewage and liquid disposable waste from the plant.
 - (3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
 - (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
 - (5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.
- (c) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.
- (d) *Toilet facilities.* Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
- (1) Maintaining the facilities in a sanitary condition.
 - (2) Keeping the facilities in good repair at all times.
 - (3) Providing self-closing doors.
 - (4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).
- (e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
- (1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
 - (2) Effective hand-cleaning and sanitizing preparations.

- (3) Sanitary towel service or suitable drying devices.
- (4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
- (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
- (6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.
- (f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C—Equipment

110.40 Equipment and utensils.

- (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
- (b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt,

and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D [Reserved]

Subpart E—Production and Process Controls

110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging

materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) *Raw materials and other ingredients.* (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations.* (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w , pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable

microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 °F (7.2 °C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 °F (60 °C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in §130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the water activity (a_w) of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G—Defect Action Levels

110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[51 FR 24475, June 19, 1986, as amended at 61 FR 14480

Appendix B

Required Label Statements

The law states that required label information must be conspicuously displayed and in terms that the ordinary consumer is likely to read and understand under ordinary conditions of purchase and use.

Details concerning type sizes, location, etc., of required label information are contained in FDA Regulations [21 CFR 101], which cover the requirements of both the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. Information for ordering copies of the Code of Federal Regulations (CFR) and Federal Register (FR) are given at the end of this section. Food labeling requirements of the regulations are summarized as follows:

1. The name, street address, city, state and ZIP code of either the manufacturer, packer or distributor. A firm listed in a current city or telephone directory may omit the street address. If the food is not manufactured by the person or company whose name appears on the label, the name must be qualified by “Manufactured for,” “Distributed by” or a similar expression.
2. An accurate statement of the net amount of food in the package. The level of any food in package form must bear an accurate declaration of the contents in terms of weight, measure or numerical count. Proposed regulations that would require the statement of quantity of contents to be expressed in terms of the metric system have not been made final, and such a declaration is presently optional. Current regulations require the net quantity of contents to be declared in the inch-pound system (avoirdupois pound and the U.S. gallon), and in dual fashion on packages containing 16 ounces but less than 4 pounds or 1 gallon. For example, the contents of a 1-pound package of cake mix could properly be declared: “Net wt. 24 oz. (1 lb. 8 oz),” “Net wt. 24 oz. (1 lb.)” or “Net wt. 24 oz (1.5 lb).” The declaration must appear on the principal display panel of the label in lines generally parallel to the base of the package as displayed for sale, and if the principal display panel exceeds 5 square inches, the declaration must appear in the lower 30 percent of the label. The declaration must appear as a distinct item in legible boldface print or type in distinct contrast

to other matter, and appropriately separated from all other printed matter on the label. Details of minimum type size, contrast, placement and separation are all set forth at 21 CFR 1.24, and 101.105.

Declaration of contents by numerical count only is limited to a few commodities, such as fresh-shell eggs. Drained weight, rather than net weight, is required on some products packed in a liquid that is not consumed as food, such as olives in brine.

3. The common or usual name of a food must appear on the principal display panel, in bold type and in lines generally parallel to the base of the package as it is displayed. The form of the product must also be included — “sliced,” “whole” or “chopped” (or other style) — unless shown by a picture or unless the product is visible through the container.
4. The ingredients in all processed, packaged food products must be listed by their common names in descending order. (Beginning May 1993, all standardized foods are required to list ingredients.) Also, the ingredient list must include, when appropriate:
 - FDA-certified color additives, by name (i.e., FD&C Yellow No. 6); butter, cheese and ice cream are exempt from this provision. (For regulations regarding declaration of ingredients specifically related to dairy products, see detailed regulations in Code of Federal Regulations.) Colors exempt from certification, such as caramel, paprika and beet juice, do not have to be specifically identified; they can still be listed simply as “artificial colors.”
 - sources of protein hydrolysates.
 - declaration of caseinate as a milk derivative in foods that claim to be non-dairy.
 - declaration of sulfiting agents (if concentration is greater than 10 ppm).

In addition, the revised labeling law allows for the voluntary inclusion of the food source in the name of sweeteners (i.e., corn sugar monohydrate).

5. Nutrition labeling is required for all processed, packaged foods except plain coffee and tea; some spices, flavorings and other foods that contain no significant amounts of nutrients (defined as those which mandatory nutrients can be labeled as 0 per defined serving); ready-to-eat food prepared primarily on site, such as deli and bakery items; donated food items; vended food; bulk food that is not for distribution to consumers in such form; and food produced by small businesses (defined by FDA as one with food sales of less than \$50,000 a year or total sales of less than \$500,000). To apply for a small business exemption, you must employ less than 100 employees, produce less than 100,000 units sold in a 12-month period, and make no nutritional claims. If a person is *not an importer*, and has fewer than 10 full-time equivalent employees, that person does not have to file a notice for any food product with annual sales of fewer than 10,000 total units. Medical foods and infant foods have specific regulations that define their nutrition label requirements and are not included in the Nutrition Labeling and Education Act of 1990.

Alternate nutrition labeling regulations apply to the following products: foods for children less than 2 years of age; exported foods; game meats; shell eggs; foods sold from bulk containers; unit containers in a multi-unit retail package; packaged single-ingredient and fish.

Foods in small packages (less than 12-square-inches total package area) are not required to have nutrition information on their labels, unless they make a nutrition claim. However, FDA-regulated products must carry a telephone number or address consumers can use to get required nutrition information.

The nutrition label format is designed to help consumers make more informed food choices. The regulations describe acceptable format, specifying: type size, style, color and placement; rule (line) placement and point size; information box dimensions, color and appropriate background.

The nutrition label panel is entitled “Nutrition Facts” and includes the following mandatory nutrients expressed as total amount per serving size and as percent of the Daily Value based upon 2,000 calories intake a day: calories; calories from fat; total fat; saturated fat; cholesterol; sodium; total carbohydrate; dietary fiber; sugars; protein; vitamin A; vitamin C; calcium; and iron. In addition, the following nutrients can be included on a voluntary basis: calories from saturated fat; stearic acid; polyunsaturated fat; monounsaturated fat; potassium; soluble fiber; insoluble fiber; sugar alcohols; other carbohydrates; and percent of vitamin A present as beta-carotene. These mandatory and voluntary components are the only ones allowed on the nutrition panel; they must appear on the nutrition panel in the specified format and order.

Serving size is the basis for reporting each nutrient’s amount. Serving sizes for specific food categories are defined by FDA in “Reference amounts customarily consumed per eating occasion: General food supply.” Both household measure and gram amount of serving size must be included on the nutrition label (for example, the serving size for small curd cottage cheese is 1/2 cup [105 g]).

Usage of nutrient descriptive terms is specifically defined in the regulations. Core terms defined in these regulations include: free, low, lean, extra lean, high, good source, reduced, less, light/lite, fewer and more. In addition, specified synonyms can be substituted for these core terms if the product complies with the guidelines for the related core term (for example, “without” may be used instead of “free”). For a complete list of approved descriptive terms and their synonyms, see detailed regulations.

Health claims have been defined for use on food labels. Appropriate health claims use “may” or “might” when describing the relationship between the nutrient and disease; they do not quantify the degree of risk reduction and indicate that the disease depends on many factors. Every statement, phrase or symbol on a label (health claim or not) must be truthful and not misleading.

Health claims approved for usage on food labels include those describing a relationship between:

- Calcium and reduced risk of osteoporosis.

- Sodium and an increased risk of hypertension (high blood pressure).
- Dietary saturated fat and cholesterol and increased risk of coronary heart disease.
- Dietary fat and an increased risk of cancer.
- Fiber-containing grain products, fruits and vegetables and a reduced risk of cancer.
- Fruits, vegetables and grain products that contain fiber, particularly soluble fiber and a reduced risk of coronary heart disease.
- Fruits and vegetables and a reduced risk of cancer.

To qualify for labeling with a health claim, foods must contain:

1. a nutrient (such as calcium), the consumption of which at a specified level as part of an appropriate diet will have a positive effect on the risk of disease, or
2. a nutrient of concern (such as fat) below a specified level. In addition, these foods must provide at least 10 percent of the Daily Value (DV) of one or more of the following naturally occurring nutrients: vitamin A, vitamin C, iron, calcium, protein and fiber. This 10 percent of daily value cannot be met by supplementation of the food item.

Lastly, foods bearing a health claim must not contain any nutrient or food substance in an amount that increases risk of disease or health condition for example, whole milk, which is high in calcium, may not bear a calcium-osteoporosis claim because its fat content exceeds the disqualifying levels, and excess fat increases risk of cancer and heart disease.

Appendix C

PURPOSE (MARK ONE)

- REGULAR
- FOLLOW-UP
- COMPLAINT
- CONSULTATION
- TRAINING/AUDIT
- OTHER
- CHANGE
- NEW
- OOB
- MFG/WH/GD

TENNESSEE DEPARTMENT OF AGRICULTURE

Regulatory Services
 Food and Dairy Section
 P.O. Box 40627 Melrose Station
 Nashville, Tennessee 37204
 Phone #: 615-837-5193 Fax #: 615-837-5335

- PERMIT POSTED
- CORRECT FEE
- PUBLIC WATER
- PUBLIC SEWER
- GAS PUMPS
- SCALES
- PLANTS
- PLANT LICENSE
- CRITICAL LETTER
- INSP RPT AVAIL

FOOD ESTABLISHMENT INSPECTION

NAME		OWNER	FOLLOW-UP DATE	
ADDRESS		CITY	ZIP	LID
MAIL ADDRESS		CITY	ZIP	PHONE

INSP. NO.	ESTAB. NO.	INSP. DATE	INSP. TIME	CO. #	TYPE	DOLLARS	SM	TOB	MISC
0-0-0-0	0-0-0-0	0-0-0-0-0-0	0-0-0-0	0-0	0-0-0-0	0-0-0-0	0-0	0-0	0-0-0-0
1-1-1-1	1-1-1-1	1-1-1-1-1-1	1-1-1-1	1-1	1-1-1-1	1-1-1-1	1-1	1-1	1-1-1-1
2-2-2-2	2-2-2-2	2-2-2-2-2-2	2-2-2-2	2-2	2-2-2-2	2-2-2-2	2-2	2-2	2-2-2-2
3-3-3-3	3-3-3-3	3-3-3-3-3-3	3-3-3-3	3-3	3-3-3-3	3-3-3-3	3-3	3-3	3-3-3-3
4-4-4-4	4-4-4-4	4-4-4-4-4-4	4-4-4-4	4-4	4-4-4-4	4-4-4-4	4-4	4-4	4-4-4-4
5-5-5-5	5-5-5-5	5-5-5-5-5-5	5-5-5-5	5-5	5-5-5-5	5-5-5-5	5-5	5-5	5-5-5-5
6-6-6-6	6-6-6-6	6-6-6-6-6-6	6-6-6-6	6-6	6-6-6-6	6-6-6-6	6-6	6-6	6-6-6-6
7-7-7-7	7-7-7-7	7-7-7-7-7-7	7-7-7-7	7-7	7-7-7-7	7-7-7-7	7-7	7-7	7-7-7-7
8-8-8-8	8-8-8-8	8-8-8-8-8-8	8-8-8-8	8-8	8-8-8-8	8-8-8-8	8-8	8-8	8-8-8-8
9-9-9-9	9-9-9-9	9-9-9-9-9-9	9-9-9-9	9-9	9-9-9-9	9-9-9-9	9-9	9-9	9-9-9-9

Items cited identify violations of State Statute which must be corrected by the next routine inspection or such shorter period of time as may be specified by the regulating authority. Failure to comply with any time limits for corrections specified in this NOTICE may result in cessation of your operations, and/or civil penalties. TCA 53-1-103; 53-8-217; 4-3-204.

The most current inspection report must be kept available at the facility for public disclosure to any person who requests to review it.

ITEM	DESCRIPTION	WT.	SCORE
FOOD			
<input type="checkbox"/> 01	Source: sound condition	5	
<input type="checkbox"/> 02	Original container, properly labeled	1	
FOOD PROTECTION			
<input type="checkbox"/> 03	Potentially hazardous food meets temperature requirements during storage, preparation, display, transportation	5	
<input type="checkbox"/> 04	Facilities to maintain product temperature	4	
<input type="checkbox"/> 05	Thermometers provided and conspicuous, accurate	1	
<input type="checkbox"/> 06	Potentially hazardous food properly thawed	2	
<input type="checkbox"/> 07	Cross-contamination prevented: damaged/detained food segregated	4	
<input type="checkbox"/> 08	Food protection during storage, preparation, display, dispensing, packaging, transportation	2	
<input type="checkbox"/> 09	Handling of food (ice) minimized	2	
<input type="checkbox"/> 10	In use, food dispensing utensils properly stored	1	
PERSONNEL			
<input type="checkbox"/> 11	Personnel with infections restricted	5	
<input type="checkbox"/> 12	Hands washed and clean, good hygienic practices	5	
<input type="checkbox"/> 13	Clean clothes, hair restraints	1	
FOOD EQUIPMENT & UTENSILS			
<input type="checkbox"/> 14	Food contact surfaces: designed, constructed, maintained, installed, located	2	
<input type="checkbox"/> 15	Non-food contact surfaces: designed, constructed, maintained, installed, located	1	
<input type="checkbox"/> 16	Warewashing facilities: designed, constructed, maintained, installed, located, operated	2	
<input type="checkbox"/> 17	Accurate thermometers, and chemical test kits provided	1	
<input type="checkbox"/> 18	Pre-flushed, scraped, soaked	1	
<input type="checkbox"/> 19	Wash, rinse water: clean, proper temperature	2	
<input type="checkbox"/> 20	Sanitization rinse: clean, temperature, concentration, time, equipment, utensils sanitized	4	
<input type="checkbox"/> 21	Wiping cloths: clean, use restricted, stored	1	
<input type="checkbox"/> 22	Food-contact surfaces of equipment and utensils clean, free of abrasives, detergents	2	
<input type="checkbox"/> 23	Non-food contact surfaces of equipment and utensils clean	1	
<input type="checkbox"/> 24	Clean equipment/utensils: storage, handling	1	
<input type="checkbox"/> 25	Single-service articles, storage, handling	1	
<input type="checkbox"/> 26	No re-use of single articles	2	
WATER			
<input type="checkbox"/> 27	Source: sufficient supply, hot & cold; under pressure	5	
SEWAGE			
<input type="checkbox"/> 28	Sewage and waste water disposal	4	
PLUMBING			
<input type="checkbox"/> 29	Installed, maintained	1	
<input type="checkbox"/> 30	Cross-connection, back siphonage, backflow	5	
TOILET & HANDWASHING FACILITIES			
<input type="checkbox"/> 31	Number, convenient, accessible, designed, installed	4	
<input type="checkbox"/> 32	Toilet rooms: enclosed, self-closing doors. Fixtures: good repair, clean. Tissue, hand cleanser, sanitary towels/hand-drying devices and proper waste receptacles provided	2	
GARBAGE & REFUSE DISPOSAL			
<input type="checkbox"/> 33	Containers or receptacles: covered, adequate number, insect/rodent resistant, pick-up frequency, clean	2	
<input type="checkbox"/> 34	Outside storage area and enclosures: properly constructed, clean; controlled incineration	1	
INSECT, RODENT, ANIMAL CONTROL			
<input type="checkbox"/> 35	Presence of insects/rodents—outer openings protected, no animals	4	
FLOORS, WALLS & CEILINGS			
<input type="checkbox"/> 36	Floors: constructed, drained, clean, good repair, covering installation, dustless methods	1	
<input type="checkbox"/> 37	Walls, ceilings: attached equipment, constructed, clean, good repair, surfaces, installation, dustless methods	1	
LIGHTING			
<input type="checkbox"/> 38	Lighting provided as required. Fixtures shielded	1	
VENTILATION			
<input type="checkbox"/> 39	Rooms and equipment—vented as required	1	
DRESSING ROOMS			
<input type="checkbox"/> 40	Rooms, area, lockers: provided, located, used	1	
OTHER OPERATIONS			
<input type="checkbox"/> 41	Toxic items: necessary; properly stored, labeled, used	5	
<input type="checkbox"/> 42	Premises maintained free of litter, unnecessary articles, cleaning, maintenance equipment properly stored	1	
<input type="checkbox"/> 43	Complete separation from living/sleeping quarters, laundry	1	
<input type="checkbox"/> 44	Clean, soiled linen properly stored	1	

*CRITICAL ITEMS MUST BE CORRECTED AS SOON AS POSSIBLE AND NO LATER THAN TEN (10) DAYS. COMMISSIONER MUST BE NOTIFIED WITHIN FIFTEEN (15) DAYS OF SUCH.

INSPECTOR	RECEIVED BY	TIME	DATE
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Appendix D

Resources

Tennessee Department of Agriculture
Regulatory Services, Food and Dairy Section
P. O. Box 40627
Melrose Station
Nashville, TN 37204
Phone: 615-837-5193
Fax: 615-837-5335

Tennessee Department of Agriculture
Market Development
Holeman Bldg.
P. O. Box 40627
Nashville, TN 37204
Phone: 615-837-5160
Fax: 615-837-5194

Division of General Environmental Health
Department of Health
Cordell-Hull Bldg.
425 Fifth Avenue, N. Sixth Floor
Nashville, TN 37247-3901
Phone: 615-741-7206
Fax: 615-741-8510

Tennessee Department of Economic and Community
Development
Research Office
William R. Snodgrass Tennessee Tower
312 Eighth Ave. N., 10th Floor
Nashville, TN 37243-0405
Phone: 615-741-1995
Fax: 615-532-5239

UT Extension
The University of Tennessee
2509 River Drive
114 McLeod
Knoxville, TN 37996-4539
Phone: 865-974-7274
Fax: 865-974-7332

Center for Profitable Agriculture
University of Tennessee Extension
P.O. Box 1819
Spring Hill, TN 37174-1819
Phone: 931-486-2777
Fax: 931-486-0141

USDA Meat & Poultry Inspection Section
100 Alabama Street, Bldg. 1924, Suite 3R-90
Atlanta, GA 30303
Phone: 404-562-5900
Fax: 404-562-5877

USDA Food and Safety Service
District 18
715 South Pear Orchard Road
Ridgeland, MS 39157
Phone: 601-965-4312 or 800-647-2484
Fax: 601-965-4993 or 601-965-5905

Small Business Administration (SBA)
409 Third St. SW
Washington, DC 20416
Phone: 202-606-4000
Fax: 202-606-4225

Tennessee Small Business Office
Department of Economic and Community Development
William R. Snodgrass Tennessee Tower
312 Eighth Ave., N., 11th Floor
Nashville, TN 37243-0405
Phone: 615-741-2626 or 800-872-7201
Fax: 615-532-8715

Appendix E

Tennessee Small Business Development Centers

Online Counseling

Phone: 931-372-3670

Alamo

Crockett County Chamber of Commerce

29 N. Bells St.

Alamo, TN 38001

Phone: 731-286-3201

Bristol

TSBDC at East Tennessee State University Bristol Field Office

Bristol Tennessee-Virginia Chamber of Commerce

20 Volunteer Parkway

Bristol, TN 37620

Phone: 423-439-8505

Chattanooga

TSBDC at Chattanooga State Community College

Business Development Center

100 Cherokee Blvd., Suite 202

Chattanooga, TN 37405-0880

Phone: 423-756-8668

Clarksville

TSBDC at Austin Peay State University

601 College St., McReynolds Bldg.

Offices 111 and 113

Clarksville, TN 37040

Phone: 931-221-1370

Cleveland

TSBDC at Cleveland State Community College
Technology Bldg.
3535 Adkisson Drive
Cleveland, TN 37320-3570
Phone: 423-478-6247

Columbia

TSBDC at Middle Tennessee State University
Columbia Satellite Office
Maury Alliance
106 W. Sixth St.
Columbia, TN 38402
Phone: 931-388-2155

Cookeville

TSBDC at Tennessee Tech University
College of Business Administration
1105 N. Peachtree
Cookeville, TN 38505
Phone: 931-372-3648

Covington

TSBDC at Dyersburg State Community College
Jimmy Naifeh Center
Learning Resource Center
3149 Highway 51 S.
Covington, TN 38011
Phone: 731-286-3201

Dyersburg

TSBDC at Dyersburg State Community College
1510 Lake Road
Dyersburg, TN 38024-2411
Phone: 731-286-3201

Elizabethton and Carter County

TSBDC at East Tennessee State University
Elizabethton Field Office
Elizabethton Chamber of Commerce
500 Veterans Memorial Parkway
Elizabethton, TN 37643
Phone: 423-547-3850

Gallatin

TSBDC at Volunteer State Community College
Betty Gibson Hall
1480 Nashville Pike
Gallatin, TN 37066
Phone: 615-230-4780

Greeneville

TSBDC at East Tennessee State University
Greeneville Field Office
Greene County Partnership Bldg.
115 Academy St.
Greeneville, TN 37743
Phone: 423-439-8505

Hardeman County Chamber of Commerce
118 S. Main St.
Bolivar, TN 38008
Phone: 731-658-6554

Haywood County Chamber of Commerce
121 W. Main St.
Brownsville, TN 38012
Phone: 731-772-2193

Wayne County ECD Office
Columbia State Community College
795 Main St.
Clifton, TN 38345
Phone: 931-676-3118

Chester County Chamber of Commerce
130 E. Main St.
Henderson, TN 38340
Phone: 731-989-5222

Jackson Area Chamber of Commerce/TSBDC (JSCC)
197 Auditorium St.
Jackson, TN 38301
Phone: 731-423-2200

Henderson County Chamber of Commerce
149 Eastern Shores Drive
Lexington, TN 38351
Phone: 731-968-2126

Decatur County Chamber of Commerce
201 S. Tennessee Ave.
Parsons, TN 38363
Phone: 731-847-4202

Hardin County Chamber of Commerce
320 Main St.
Savannah, TN 38372
Phone: 731-925-2363

McNairy Regional Alliance
Chamber of Commerce/Regional Alliance Bldg.
144 Cypress Ave.
Selmer, TN 38375
Phone: 731-645-6360

Whiteville TTC
1685 Highway 64 W.
Whiteville, TN 38075
Phone: 731-254-8521

Johnson City

TSBDC at East Tennessee State University
Main Office
ETSU Innovation Laboratory
2109 W. Market St.
Johnson City, TN 37604
Phone: 423-439-8505

Kingsport

TSBDC at East Tennessee State University
Kingsport Affiliate Office
Kingsport Area Chamber of Commerce — KOSBE Office
400 Clinchfield St., Suite 100
Kingsport, TN 37660
Phone: 423-392-8825

Knoxville

Blount County Chamber Partnership
201 S. Washington St.
Maryville, TN 37804
Phone: 865-983-2241

Pellissippi State Community College
10915 Hardin Valley Road
Knoxville, TN 37933
Phone: 865-246-2663

Farragut West Knoxville Chamber of Commerce
11826 Kingston Pike
Knoxville, TN 37934
Phone: 865-675-7057

Lebanon

Lebanon Wilson County Chamber of Commerce
149 Public Square
Lebanon, TN 37087
Phone: 615-444-5503

Martin

Benton County Chamber of Commerce
202 W. Main St.
Camden, TN 38320
Phone: 731-587-7333

Humboldt Chamber of Commerce
1200 Main St.
Humboldt, TN 38343
Phone: 731-587-7333

Carroll County Chamber of Commerce
20740 E. Main St.
Huntingdon, TN 38344
Phone: 731-587-7333

TSBDC at the University of Tennessee at Martin
REED Center
406 S. Lindell St.
Martin, TN 38237
Phone: 731-587-7333

Milan Chamber of Commerce
1061 S. Main St.
Milan, TN 38358
Phone: 731-587-7333

Memphis

TSBDC at Southwest Tennessee Community College
Parrish Bldg., Room 134
737 Union Ave.
Memphis, TN 38103
Phone: 901-333-5085

TSBDC at the STCC Satellite Office
Memphis Renaissance Center
555 Beale St.
Memphis, TN 38103
Phone: 901-526-9300

Murfreesboro

TSBDC at Middle Tennessee State University
Rutherford County Chamber of Commerce
3050 Medical Center Parkway
Murfreesboro, TN 37129
Phone: 615-898-2745

Nashville

TSBDC at Tennessee State University
Avon Williams Campus/Downtown
330 10th Ave. N.
Nashville, TN 37203-3401
Phone: 615-963-7179

TSBDC at Tennessee State University
Brentwood Satellite Office
Reliant Bank
1736 Carothers Parkway, Suite 100
Brentwood, TN 37027
Phone: 615-963-7179

Oak Ridge

Roane State Community College at Oak Ridge
Chamber of Commerce
1400 Oak Ridge Turnpike
Oak Ridge, TN 37830
Phone: 865-483-2668

Oak Ridge Chamber of Commerce
1400 Oak Ridge Turnpike
Oak Ridge, TN 37830
Phone: 865-483-2668

Ripley

Lauderdale County Chamber/ECDC Bldg.
123 S. Jefferson St.
Ripley, TN 38063
Phone: 731-286-3201

Robertson County

Robertson County Chamber of Commerce
503 W. Court Square
Springfield, TN 37172
Phone: 931-221-1371

Rogersville

TSBDC at East Tennessee State University
Rogersville Field Office
Rogersville/Hawkins County Chamber of Commerce
U.S. Bank Bldg.
107 E. Main St.
Rogersville, TN 37857
Phone: 423-439-8505

Tipton County

South Tipton Chamber of Commerce
1286 Munford-Atoka Ave.
Munford, TN 38058
Phone: 901-837-4600

Union City

Obion County Library
1221 E. Reelfoot Ave.
Union City, TN 38261
Phone: 731-885-7000

What determines how your food product will be regulated?

1. One of the key elements in determining how your food will be regulated is the acid content of the food. The strength of the acid is measured in terms of pH. Therefore, one should understand the meaning of pH and its significance in foods. pH measurement of acid strength is reported on a scale of 0-14.0, with neutral being 7.0 (meaning this is neither acid or basic). Any pH number below 7.0 means the product is on the acid side of the pH scale; if a number is above 7.0 it is on the basic side of the scale. Very few foods have a pH of 7.0 or greater. The vast majority of food has a pH range of approximately 2.5-6.0.
2. Since most foods have a pH below 7.0, this would indicate they are all acidic in nature. This is not true, however. In food science, we have drawn the line between “low-acid” food and “acid” food at a pH of 4.6. “Low-acid” foods have a pH of 4.6 or greater. These include foods such as meat, poultry, seafood, milk and fresh vegetables (except for tomatoes). “Acid” foods have a pH of 4.6 or lower. These include foods like jams and jellies, barbeque sauces, most salad dressings and most fruits.
3. In the food processing business, we also have a number of foods that are inherently low in acid, (i.e., cucumbers, okra, cauliflower, peppers, etc.) that have acid added as part of the process to make a pickled product. These foods are classified as “Acidified Foods” and are regulated under a different set of guidelines.

Visit the UT Extension website at
<http://www.utextension.tennessee.edu>

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