

Getting Started in a Food Manufacturing Business in Tennessee



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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 busi-

nesses, 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. Com-

petition 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 salmonellae, staphylococci, 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 which cause illness thrive in the range between 40 degrees and 140 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.

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 potential business entrepreneurs, 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 are easily read in Factsheet SP351B, *A Beginning Guide to Starting a Business*, published by the University of Tennessee Agricultural Extension Service, and the *Small Business Information*¹ book, published by Tennessee Department of Economic and Community Development.

¹*Small Business Information, Tennessee Department of Economic and Community Development, Rachel Jackson Building, 8th Floor, 320 6th Ave., North, Nashville, TN 37243-0405. ph. (615)741-1995.*

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.

- a. Evaluate your personal characteristics.
- b. Develop a business idea.
- c. Write a business plan.
- d. Translate the idea into distinct consumer benefits.
- e. Evaluate the competition.
- f. Redefine and improve your idea.
- g. Examine market conditions.
- h. Design the smallest possible viable business unit.
- i. 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 is also the legal responsibility of the owner of any business.

In the planning stages, you should initially 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 the state of Tennessee. All foods prepared at any location, including the home, for sale to consumers, distribution or retailers fall under the responsibility of both the state Department of Agriculture (TDA) and the local county health department. A catering business operated from the home will be approved and regulated by the Tennessee Department of Health and Environment (TDH&E).

To be sure you are familiar with all the required regulations, read and understand the Tennessee Food, Drug and Cosmetic Act, Good Manufacturing Practices (GMP's) - Appendix A, and the packaging and labeling regulations - 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 Quality and Standards Division, Food and Drug Section, Tennessee Department of Agriculture, P.O. Box 40627, Melrose Station, Nashville, Tennessee 37204, ph. (615)362-0193.

Tennessee regulations specifically state that food prepared on home premises must meet the same requirements as any commercial food manufacturing plant. Also, no operation of a food service establishment (or retail food store) shall be conducted in any room used as living or sleeping quarters. This means that a kitchen used for family cooking can not also be used to prepare food for sale. 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 is also 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 Quality and Standards 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 are obtainable from the Food and Drug Administration, Industry Guidance Branch (HFF-326), 200 C. Street, SW, Washington, D.C. 20204.



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

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 approval of these plans by the state, construction may begin and be completed. If changes are made in the originally approved plans, these 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 Meat Inspection.

In the early stages of your business it is wise to utilize 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 address and telephone numbers is in Appendix E. The Tennessee Department of Agriculture Division of Marketing is a resource made available to new and existing businesses to assist in marketing their products. The marketing division can include your business in their resource directory and 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&E 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 the State of Tennessee

There are basically three types of permits issued in Tennessee, depending on the type of food business you are involved in. Listed below are the three different 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 and Environment, Division of Food and General Sanitation, TERRA Bldg., 150 9th Ave. North, Nashville, TN 37219, ph. (615) 741-7266.
2. **Food Service Establishment Permit** - Issued by the Tennessee Department of Health and Environment. It covers all restaurants.
3. **Wholesale and Manufacturing Processing Plants** - These are regulated by the TDA but there is no “permit” issued. They are issued a copy of the TDA, Quality and Standards Division, Food and Drug Section’s “Inspection Report” **before** the process is started (Appendix C).

4. 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 contracts inspection in Davidson, Knox and Shelby counties.
 - f. All consumer complaints are responded to by calling 360-0193 outside Davidson County; 340-5620 (Metro Health Dept.) in Davidson County.
 - g. Food samples are routinely picked up and checked for, among others: E.coli, Listeria, fat content, species identification, aflatoxin, pesticide residue.
 - h. All retail food stores are required by law to have a permit posted conspicuously, and to also have the most current 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 that have 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- & 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 may also 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, also for extensive remodeling.
- n. The department also inspects approximately 600 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 department does not contract inspection for the U.S. Food and Drug Administration.

IV. Effluent and Waste Water

In most food processing facilities there is a certain amount of waste generated. This can be in a 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 facility. Food processing wastes can be a substantial ecological hazard to our environment. It is also against the 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 a solid waste, 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 department of health and environment.

V. Good Manufacturing Practices

Under the authority of Section 52-121 of the Tennessee Code Annotated (the Food, Drug and Cosmetic Act), the Commissioner of Agriculture has determined that the conformity with good manufacturing practices (GMP's) is essential for the production of food for human consumption. Good manufacturing practices were designed and instituted by the federal government to assure that foods are manufactured, processed and handled in a safe and sanitary manner. The conditions as set forth in the GMP's must be met to operate and maintain your business. If a complaint is filed against you or your product, a GMP inspection by the FDA or state is likely to occur.

The GMP's are broken down into the following areas:

- a. Plant and grounds
- b. Equipment and utensils
- c. Sanitary facilities and controls
- d. Sanitary operations
- e. Processes and controls
- f. Personnel

Part of the Good Manufacturing Practices for all Food Plants are repeated in Appendix A; for additional information see the Code of Federal Regulations, CFR 21, parts 100-169.

In developing plans for your food processing facility, the Tennessee Department of Agriculture, Division of Quality and Standards, requires their 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 of

a light color, smooth, non-absorbent and easily clean able. (If concrete floors are used, they must be sealed.)

2. All fixed equipment must be sealed to 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 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 shall also 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. Provide an adequate and effective hood and exhaust system over all deep fat fryers, broilers, griddles, ranges, steam cookers and similar equipment which 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 Conservation and 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 and Environment.
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.

Please feel free to contact this office if you have any questions.

VI. Weights and Measures

Let us now direct our attention to proper net weights 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 non-food 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.
3. The common or usual name of the food.
4. The ingredients in the food.

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 Quality and Standards Division, Food and Drug 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). However, these regulations and guidelines will probably be changed in the near future. Consult the TDA or your Agricultural Extension agent for details.

VIII. UPC (Universal Product Code):

If you wish to sell your product in retail grocery chain stores, it would be advisable to obtain a UPC code for your product. This code is a series of bar codes that allows your product to be checked out at the grocery stores' automated cash registers. There is a minimum fee of \$300 to obtain a code.

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

Uniform Code Council
8163 Old Yankee Road
Suite J
Dayton, OH 45458
ph. 513-435-3870

IX. Insurance³

Insurance helps to safeguard your business against losses from fire, illness and injury. You cannot afford to operate without it. Talk with your insurance agent about your business needs. He or she can make sure business use of your home is compatible with your homeowner's policy. In addition to a homeowner's policy (personal coverage), now that you have a business, you will need a commercial lines policy for full protection. Discuss these other possible needs with your agent:

³"Managing a Home Business," Insurance Marketing Services, Lohman and Lohman, Genesco, Illinois, ph. (309)764-8331.

Product Liability Coverage - To protect you if your product causes injury to the user.

Auto Liability and “Non-owned” Auto Liability insurance - if a car is ever used to support the business in any way.

Medical Payments Insurance - payable if someone is injured in your home, whether or not it was your fault.

Workers Compensation - if you have employees.

Business Income Insurance or Earnings Insurance - if your business is damaged by fire or some other cause and you must totally or partially suspend operations.

Disability Income Protection - a form of health insurance in case you become disabled.

Business Life Insurance - to provide funds for transition upon your death.

Be sure to keep all 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's sake, then give your policy numbers and insurance company names to your accountant or lawyer or put a list in your safe deposit box.

Final advice for the wise business person is to read and understand the fine print in all policies and to re-evaluate 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. In addition, the Tennessee Valley Authority (TVA) has a cost sharing competitive bid program for the development of agriculture which may help with funding. 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 to 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 \$245 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 can be obtained from:

Assistant Commissioner for Trademarks
Arlington, Virginia 22202
Ph. 1-800-786-9919

XII. 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 where 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.

There are a multitude of technical resources at your disposal. It will be your responsibility to utilize 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. Specialists can 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 Extension sections of food technology and science, agricultural economics and resource development, plant and soil science, and agricultural engineering at the University of Tennessee can all be valuable assets to a beginning food business. Other excellent resources are the TDA, FDA, ECD and TDH&E. Appendix D gives a more complete list of resources that you will find useful.

Appendix A

Part 110 - Current Good Manufacturing Practices In Manufacturing, Processing, Packing, Or Holding Human Food

Subpart A - General Provisions

Sec

110.1 **Current good manufacturing practices.**

110.3 **Definitions.**

110.10 **Personnel.**

110.19 **Exclusions.**

Subpart B - Buildings and Facilities

110.20 **Plants and Grounds.**

110.35 **Sanitary facilities and controls.**

110.37 **Sanitary operations.**

Subpart C - Equipment

110.40 **Equipment and Procedures.**

Subpart D - [Reserved]

Subpart E - Production and Process Controls

110.80 **Processes and controls.**

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

AUTHORITY: Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055 (21 U.S.C. 342(a)(4), 371(a), unless otherwise noted.

SOURCE: 42 FR 14338, Mar. 15, 1977, unless otherwise noted.

Subpart A - General Provisions

110.1 **Current good manufacturing practice.**

The criteria in 110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80 and 110.99 shall apply in determining

whether the facilities, methods, practices and controls used in the manufacture, processing, packing or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

110.3 **Definitions.**

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

- (a) "Adequate" means that which be needed to accomplish the intended purpose in keeping with good public health practice.
- (b) "Plant" means the building or buildings or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling or holding of human food.
- (c) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other microorganisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

110.10 **Personnel.**

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

- (a) Disease Control. No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.
- (b) Cleanliness. All persons, while working in direct contact with food preparation, food ingredients or surfaces coming into contact therewith shall:

- (1) Wear clean outer garments, maintain a high degree of personal cleanliness and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.
 - (2) Wash their hands thoroughly (and sanitize if necessary to prevent contamination by 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.
 - (3) Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.
 - (4) If gloves are used in food handling, maintain them in an intact, clean and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.
 - (5) Wear hair nets, headbands, caps or other effective restraints.
 - (6) Do not store clothing or other personal belongings, eat food or drink in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.
 - (7) Take any other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals and medicants.
- (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 cognizant 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 110 shall be clearly assigned to competent supervisory personnel.

110.19 Exclusions.

The following operations are excluded from coverage under these general regulations; however, the Commissioner will issue special regulations when he believes it necessary to cover these excluded operations: 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.

Subpart B - Buildings and Facilities

- (a) Grounds. The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including, but not limited to, the following:
 - (1) Improperly stored equipment, litter, waste, refuse and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests.
 - (2) Excessively dusty roads, yards or parking lots that may constitute a source of contamination in areas where food is exposed.
 - (3) Inadequately drained areas that may contribute contamination to food products through seepage or food-borne filth and by providing a breeding place for insects or microorganisms.

If the plant grounds are bordered by grounds not under the operator's control of the kind described in paragraphs (a) (1) through (3) of this section, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt and other 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-processing purposes. The plant and facilities shall:
- (1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be adequately cleanable and shall be kept clean and in good repair. Fixtures, ducts, and pipes shall not be so suspended over working areas that drip and condensate may contaminate foods, raw materials, or food-contact surfaces. Aisles or working spaces between equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of food or food-contact surfaces with clothing or personal contact.
 - (2) Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable microorganisms, chemicals, filth or other extraneous material.
 - (3) Provide adequate lighting to handwashing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.
 - (4) Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.
 - (5) Provide, where necessary, effective screening or other protection against birds, animals and vermin (including, but not limited to, insects and rodents).

110.35 **Sanitary facilities and controls**

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

- (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 foods 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 the processing of food, the cleaning of equipment, utensils, or containers, or employee sanitary facilities require.
- (b) **Sewage disposal.** Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.
- (c) **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) Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment or utensils or create an insanitary 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.
- (d) **Toilet facilities.** Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. Toilet rooms shall be furnished with toilet tissue. The facilities shall be maintained in sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is

exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using toilet.

- (e) Hand-washing facilities. Adequate and convenient facilities for hand washing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at a suitable temperature for hand washing, preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.
- (f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces and water supplies.

110.37 **Sanitary operations**

- (a) General maintenance. Buildings, fixtures and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.
- (b) Animal and vermin control. No animals or birds, other than those

essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by but not limited to, rodents and indenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.

- (c) Sanitation of equipment and utensils. All utensils and product-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Nonproduct-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) should be stored in appropriate containers and handled, dispensed, used and disposed of in a manner that prevents contamination of food or food-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surface may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.
- (d) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment and utensils with product-contact surfaces should be stored in such a location and manner that product-contact surfaces are protected from splash, dust and other contamination.

Subpart C - Equipment

110.40 Equipment and procedures

- (a) General. All plant equipment and utensils should be (1) suitable

for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construction, and use of such 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.

(b) Use of polychlorinated biphenyls in food plants. Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) ON or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment

or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's.

- (ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.
 - (iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.
 - (iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (d) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis.
- (3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart D - [Reserved]

Subpart E - Production and Process Controls

110.80 Processes and Controls

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accord with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that production procedures do not contribute contamination such as filth, harmful chemicals, undesirable microorganisms or any other objectionable material to the processed product:

- (a) Raw material and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying products in a manner that may result in contamination of food products.
- (b) Containers and carriers of raw ingredients should be inspected on receipt to assure that their condition has not contributed to the contamination and deterioration of the products.
- (c) When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported and handled in a sanitary manner.
- (d) Food-processing areas and equipment used for processing human food should not be used to process nonhuman food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.
- (e) Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
- (f) All food processing, including packaging and storage, should be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or con-

tamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of the processed products.

- (g) Chemical, microbiological or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be properly accomplished.
- (h) Packaging processes and materials shall not transmit contaminants or objectionable substances to the products, shall conform to any applicable food additive regulation (Parts 170 through 189 of this chapter), and should provide adequate protection from contamination.
- (i) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing or repacking activity should be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than 2 years.
- (j) Storage and transportation of finished products should be under such conditions as will prevent contamination, including development of pathogenic or toxigenic microorganisms, and will protect against undesirable deterioration of the product and the container.

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.** The street address may be omitted by a firm listed in a current city or telephone directory. 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 proposed revision requires the declaration of net quantity of contents in **both** the inch-pound system (avoirdupois pound and the U.S. gallon) and the metric (SI) system (kilograms and the liter). For example, net weight declaration for a package of cupcakes could be: Net Weight 4 oz. (113 g) or 113 g (4 oz.). The quantity of contents declaration must appear on the principal display panel of the label in lines generally parallel to the base of the package when displayed for sale. If the area of the principal display panel of the package is 5 square inches or less, the requirement that the net quantity be within the bottom 30 percent of the principal display panel does not apply.

Packages with a net weight between one and four pounds are no longer required to declare net weight as both ounces and pounds with decimal fractions.

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, 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). Medical foods and infant foods have specific regulations which 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 2000 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 which become effective May 1994. Core terms which are defined in these new 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; 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 which have been 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) whose consumption 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 which 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).

To obtain copies of the Federal Register and Code of Federal Regulations:

Currently, the January 1993 Federal Register is out of print; main libraries of major cities and most universities will have copies of the Federal Register on file.

The Code of Federal Regulations (stock number 869-019-00067-4) can be purchased from the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Please call (202) 783-3238 to determine availability and cost prior to ordering.

This Appendix was revised with the assistance of Katherine Smalley, Associate Professor, Tennessee Technological University, and Traci Netherton, Dietetics Student, Tennessee Technological University.

Appendix C

Appendix D

Resources

Tennessee Department of
Agriculture
Division of Quality and
Standards
P.O. Box 40627
Melrose Station
Nashville, TN 37204
ph. (615)360-0193

Tennessee Department of
Agriculture
Division of Marketing
P.O. Box 40627
Melrose Station
Nashville, TN 37204
ph. (615)360-0160

Division of Food and General
Sanitation
Dept. Of Health and Environment
TERRA Building
150 9th Avenue, North
Nashville, TN 37219
ph. (615)741-7266

Tennessee Department of
Economic &
Community Development
Rachel Jackson Building - 8th Floor
320 6th Avenue, North
Nashville, TN 37243-0405
ph. (615)741-1995

Agricultural Extension Service
U.S. Department of Agriculture
University of Tennessee
P.O. Box 1071
Knoxville, TN 37901-1071
ph. (615)974-7112

USDA Meat & Poultry
Inspection
Southeastern Regional Office
299 South, 1718 Peachtree
Street, NW
Atlanta, GA 30309
ph. (404)347-3911

USDA Meat & Poultry
Inspection
Southeastern Region Area
Supervisor
Jackson Mall Office Center, Suite
312
350 W. Woodrow Wilson Avenue
Jackson, MS 39213
ph. (601)965-4312

U.S. Food and Drug
Administration
297 Plus Park Blvd.
Nashville, TN 37217
ph. (615)781-5372 - ext. 122

Small Business
Administration (SBA)
1441 L Street, NW
Washington, DC 20416
ph. (205)386-2823
(800)653-7561

Tennessee Small Business
Office
Department of Economic &
Community Development
210 6th Avenue North, 7th
Floor Rachel Jackson Bldg.
Nashville, TN 37219
ph. (615)741-2606
(800)872-7201

Tennessee Valley
Authority
Community Partnerships
Agricultural Institute
NFE 2L, P.O. Box 1010
Muscle Shoals, AL
35661-1010
ph. (205)386-2625

Appendix E

Department of Economic and Community Development Regional Offices

Region No. 1

Northeast Tennessee Office
Tri-City Airport
Box 1022
Blountville, TN 37617
(423)323-1203

Region No. 2

Middle East Tennessee Office
531 Henley Street, 7th Floor
Knoxville, TN 37902
(423)594-6666

Region No. 3

Southeast Tennessee Office
540 McCallie Avenue
101 State Office Building
Chattanooga, TN 37402
(423)634-6376

Local Planning
540 McCallie Avenue
700 State Office Building
Chattanooga, TN 37402
(423)634-6446

Region 4

Upper Cumberland Tennessee Office
P.O. Box 2803
Cookeville, TN 38502
(615)528-8331

Local Planning
P.O. Box 2840
Cookeville, TN 38501
(615)528-1577

Region No. 5

207 North Boone Street
Middle Tennessee Office
320 6th Avenue North
Rachel Jackson Building
Nashville, TN 37219

Local Planning
624 Grassmere Drive,
Suite 11
Nashville, TN 37211
(615)741-1534

Region No. 6

West Tennessee Office
401 State Office Building
Jackson, TN 38301
ph. (901)423-5650

Region No. 7

Memphis Office
170 N. Main Street, Suite 1202
Memphis, TN 38103
ph. (901)543-7425



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