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Manufacturing Non-potentially Hazardous Foods for Sale in Tennessee Without a Permit

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Notice or Disclaimer:

The information contained in this publication is intended for educational purposes only and does not constitute legal advice or regulatory oversight.

BACKGROUND

Foods manufactured for sale in Tennessee may be regulated by the Tennessee Department of Agriculture (TDA), United States Department of Agriculture (USDA), and/or the United States Food and Drug Administration (FDA). The agency involved and the level of regulation is determined by: 1) the level of food safety risk of the product and 2) how the product is sold or distributed. Foods with higher food safety risks, such as canned foods and milk products, have a higher level of regulation and oversight. Foods sold within a state and/or only direct to consumers versus across state lines or through wholesale and retail stores have different regulations and agencies involved in the process. Most food products fall under both state and federal regulations and require an inspected facility for processing and/or packaging.

Foods classified as non-potentially hazardous have relatively less risk of causing a significant foodborne illness; therefore, regulations are less strict. Regulations in the state of Tennessee (Tennessee Code Annotated § 53-1-208) allow small food processors (i.e., those without full-time employees) to manufacture non-potentially hazardous food products to be sold direct to consumers in the state without a license/permit from the Tennessee Department of Agriculture (TDA). The USDA and FDA would not be involved in the oversight or permitting of these non-potentially hazardous foods manufactured by small processors for direct consumer sales within the state of Tennessee, assuming none of the food ingredients were sourced outside of the state.

This means that non-potentially hazardous foods sold directly to the consumer within the state may be produced in a home kitchen (often referred to as a domestic kitchen) or other non-permitted kitchen in Tennessee without requiring permitting and inspection by TDA. The limitation of selling direct to consumers is important because this means the foods cannot be sold to a retail store.

Also, the limitation that the food processor not have full-time employees limits the size of these operations. Even though no permit is required, the food products must be manufactured following current Good Manufacturing Practices (cGMPs) and other requirements including proper labeling.

As a result of this law, TDA will not issue a food manufacturing permit for a domestic kitchen. This means that any foods processed in a domestic kitchen that are offered for sale must be non-potentially hazardous foods and meet the requirements of the latest Tennessee regulations.

This publication describes the regulatory requirements and limitations for manufacturing and selling non-potentially hazardous food products through a home-based business and is intended to provide guidance to food entrepreneurs using their domestic or other non-permitted kitchen for manufacturing these products. The publication provides definitions for common terms used in food manufacturing, discusses the regulatory requirements allowing the manufacturing of non-potentially hazardous foods in a home kitchen, explains common hazards in food manufacturing, discusses the current Good Manufacturing Practices (cGMPs) and labeling requirements, and provides some recordkeeping considerations.

1. DEFINITIONS

These terms are commonly used in food manufacturing and describe important aspects of keeping food safe for consumers.

Adulteration: The contamination of a food product with any poisonous, deleterious or contaminated substance that may be injurious to health or has been produced, prepared or packaged in unsanitary conditions that could result in contamination with filth.

Big Eight Allergens: The eight major allergenic foods according to the Food and Drug Administration (FDA) are considered chemical hazards if not properly listed on any product's packaging: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybean. These ingredients must be listed in the ingredient list using these names (and for fish and tree nuts must include the species of fish or type of nut). A "Contains" statement, such as, "Contains wheat, egg, milk and coconut," may be included optionally but must list all of the major allergens that are either in the food or are contained in the ingredients of the food. Common ingredients missed are "whey," which is considered milk and "lecithin," which may be from either egg or soy.

The eight major allergenic foods:

- milk
- eggs
- fish
- crustacean shellfish
- tree nuts
- peanuts
- wheat
- soybean

Catering: Catering is the business of providing food service at a site other than where the food is prepared. Food prepared by a caterer is intended for consumption at the site of service. Catered food is not "packaged" for consumption at a later time. Catering businesses are required to register with local and/or state health departments and require an inspected kitchen for food preparation.

CFR: Code of Federal Regulations, which includes the laws enforced for food safety by the FDA (Title 21), USDA (Title 9), or EPA (Title 40).

Cross Contamination: The transfer of microorganisms or allergens from one surface or food to another.

cGMP: Current Good Manufacturing Practices (21 CFR part 117, subpart B) ecfr.gov; describes in detail regulatory requirements for personnel, production facilities, sanitary operations, equipment, processes and warehousing for producing safe foods.

Direct-to-Consumer Sales: Sales from the food processor to the consumer. For products made in a non-permitted kitchen, typical sales outlets are farmers markets, roadside stands or other venues directly operated by the food processor.

Domestic Kitchen: A home-based kitchen meeting applicable cGMPs that is used to manufacture non-potentially hazardous foods for sale to the general public.

FDA: The Food and Drug Administration is a federal government agency that regulates most processed/manufactured foods and non-meat products in the United States.

Food Establishment: Refers to retail food stores and food service establishments located within retail food stores. Food establishments require a permit in Tennessee.

Food Manufacturer: Any person (or organization) that makes food from one or more ingredients, or synthesizes, prepares, treats, modifies or manipulates food, including food crops and ingredients.

Food Service Establishment: Any establishment or place (permanent or temporary) where food is prepared and served to the public. Private homes where food is prepared or served and not offered for sale are excluded.

Hazards: Any microbiological, chemical or physical contaminant that may cause injury or illness.

Non-potentially Hazardous Foods: Includes jam, jellies, candy and baked goods that do not meet the definition of potentially hazardous foods.

Potentially Hazardous Foods: Includes those foods that consist of meat, poultry, liquid eggs and partially cooked egg products, fish, milk and milk products, shellfish, partially cooked bakery products, and/or other ingredients capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms when stored at temperatures in excess of 45 F if a cold food, or below 140 F if a hot food. Also included as potentially hazardous foods are low-acid canned foods (vegetables, fish, meat, etc.) and acidified foods (pickled vegetables, fish, meat, eggs, etc.).

Retail Food Store: An establishment where food and food products are offered to the consumer and intended for off-premise consumption. However, “retail food store” does not include establishments that handle only prepackaged, non-potentially hazardous foods.

Retail sales: Sale of products directly to the end consumer.

Shelf Life: The estimated amount of time a food remains in an acceptable condition prior to consumption by a consumer.

Traceability: The ability to identify and track sources of ingredients, suppliers and product customers.

USDA: The United States Department of Agriculture is a federal government agency that regulates red meat, poultry, egg products and products containing meat.

Water activity (A_w): A measure of the availability of water for microbiological growth and ranges from 0 (a dried product) to 1.0 (pure water). Water activity is related to the equilibrium relative humidity of air around the food product if sealed within a package. Soups, juices, etc., have water activity ~1.0; jams and jellies (high in sugar) have water activity ~ 0.80; and dried pasta and cereal products have water activities ~ 0.20.

2. REGULATORY REQUIREMENTS

The following requirements must be met under Tennessee law (Tennessee Code Annotated § 53-1-208) in order to manufacture and sell non-potentially hazardous foods without a license or inspection:

- **The products may only be sold directly to end consumers in the state of Tennessee.**
  - **Sales of products to restaurants, grocery stores, convenience stores, gift shops, etc., for resale to the public is not allowed. Sales across state lines are also not permitted.**
- **The manufacturer cannot employ regular, full-time employees for manufacturing, processing, packing or holding their product(s).** Part-time employees are permissible.
- **The processing of products must follow the cGMP regulations.** As applicable, the requirements for sanitary facilities, equipment and personnel must be followed to ensure the products are unadulterated. (See section 5 below for additional details.)
- **The products must be properly labeled.** (Refer to section 7 below for more information.)
- **The manufacturer must allow regulators to access the food manufacturing facility (kitchen and storage areas, etc.) if necessary to ensure public safety.** This would likely occur if there were a foodborne illness that was possibly linked to your products.

Tennessee Code Annotated § 53-1-208, parts b-e are provided below for further reference

(b) Except as provided in subsection (d), no person shall manufacture, process, pack, or hold food for introduction into commerce unless the person holds a valid license issued by the commissioner. Applicants for licensure shall submit an application for the license on forms provided by the commissioner. The commissioner may issue a license to an applicant only upon receipt of the proper license fee and an inspection of the applicant's facility that indicates the applicant is in compliance with the requirements of this part and the rules promulgated thereunder. Licenses issued under this section shall expire on July 1 of each year or as the commissioner may otherwise provide by rule. The commissioner shall set annual fees for licenses issued under this section by rule pursuant to § 43-1-703. Notwithstanding § 43-1-704(b), the commissioner shall set fees for licenses issued under this section on or before April 1, 2018.

(c) The commissioner shall set by rule pursuant to § 43-1-703 a fee for a certificate of free sale.

(d) No license shall be required under this section for any person who manufactures, processes, packs, or holds food for introduction into commerce, if:

(1) The food is not potentially hazardous, as defined by departmental regulation;

(2) The person is not subject to any license or permit requirements under § 53-2-107, § 53-3-105, § 53-3-106, § 53-7-216, § 53-7-220, or § 53-8-206;

(3) The person introduces food into commerce only through direct retail sales to end consumers in the state;

(4) The person employs no regular, full-time employees for the manufacturing, processing, packing, or holding of food; and

(5) Prior to introducing the food into commerce, the person labels the food in accordance with this part and regulations promulgated by the commissioner.

(e) Exemption from licensure requirements under this section shall not be construed to exempt any person from any other regulations applicable to the manufacturing, processing, packing, or holding of food for introduction into commerce, including, but not limited to, requirements regarding recordkeeping, sanitary operation, and availability for inspection by agencies charged with enforcing food safety laws.

3. COMMON HAZARDS IN FOOD MANUFACTURING

While producing non-potentially hazardous foods does not require a license or facility permit in the state of Tennessee, hazards can still be present during manufacturing and are just as dangerous as they would be in a commercially licensed facility. Anyone preparing food for sale may be held liable if his or her product causes a person harm through a foodborne illness or an allergic reaction.

Although training is not a requirement, it is highly encouraged that those interested in selling food made in a domestic kitchen participate in the **UTIA Department of Food Science Domestic Kitchen Training Course**, which is offered online at: foodscience.tennessee.edu/domestic-kitchen-training

There are three main types of hazards to be aware of and avoid when preparing, processing or packaging food items: microbiological, chemical and physical hazards. Any food containing one of these hazards is considered adulterated and should not be sold under any circumstance. If any food is found to have one of these hazards, the manufacturer's facilities may be subject to an inspection or require a permit from the Tennessee Department of Agriculture. Following good manufacturing practices (discussed in section 5) can greatly reduce these hazards in the food processing area and increase both food quality and safety.

Microbiological hazards consist of bacteria and mold that can grow in foods when they are exposed to the right conditions. Some of the more commonly known bacteria that cause foodborne illness are salmonella, E. coli, *Stapylococcus aureus*, and listeria. These bacteria can cause illness or death in some situations. Microbiological contamination usually occurs from improper temperature, moisture or humidity conditions or from improper cleaning and sanitation of equipment surfaces and the facility. It is imperative to follow all recommended storage, cleaning and sanitizing protocols to reduce the potential for contamination. If foods are heated during processing, microbiological hazards are usually minimized. Also, food with low moisture or low pH are relatively low risk for growth of microbiological hazards.

Chemical hazards include unintentional chemicals in a food most commonly through improper washing of raw food ingredients (i.e., pesticides), improper storage of chemicals or allergenic foods, and residues of cleaning or sanitizing chemicals on equipment or food contact surfaces. While there are specific chemical cleaners and sanitizers that are accepted for use in food manufacturing facilities, they are not intended to be in foods. Allergens are also a major chemical hazard and are the leading cause of food recalls in the United States. Avoiding unintentional allergens in a food (typically from an ingredient or residue left on equipment or utensils after processing a product containing the allergen) and preventing the omission of allergens from a food product label are extremely important. Proper labeling is the only way individuals with food allergies can avoid consuming the allergen. Allergic reactions to food allergens can result in serious illness and even death.

Physical hazards consist of fragments of unwanted material getting into a food ingredient or finished food product. The most common sources of physical contaminants are personal jewelry (rings, earrings, etc.); glass (from bottles or light fixtures); and metal, plastic or rubber (from processing equipment). These hazards can potentially cause choking or personal injury. Proper procedures must be in place to avoid contaminating food during manufacturing and packaging the products.

4. NON-POTENTIALLY HAZARDOUS vs POTENTIALLY HAZARDOUS FOODS

Non-potentially hazardous foods are the only foods that can legally be manufactured by small processors without a license or permit in Tennessee. Non-potentially hazardous foods do not support the growth of bacteria, and the processing steps do not require stringent time and/or temperature controls to assure a safe product. Non-potentially hazardous foods are typically naturally acidic (typically pH < 4.2), have a low water activity (Aw < 0.85), or both. Things high in sugar content, baked or dried typically have low water activity, but it depends on the actual ingredients.

There is not an exhaustive list of items that are considered non-potentially hazardous foods. A range of products are typically non-potentially hazardous; however, there are instances where recipe modifications could turn a typically non-potentially hazardous product into a potentially hazardous product.

NON-POTENTIALLY HAZARDOUS

Examples of non-potentially hazardous foods often include:

a. Baked goods that do not require refrigeration (e.g., breads, muffins, fruit pies but not custard, cream, pumpkin or sweet potato pies).

b. Fruit jams, jellies and preserves.

c. Fruit butters (apple, peach, etc.).

d. Canned fruit (naturally acidic fruits only).

e. Candy.

f. Dried baking or spice blends (e.g., oregano, thyme, rosemary, sage).

While these foods are inherently very low risk, it does not mean that they are without risk. They are still prone to cross-contamination from other foods, raw ingredients or allergens during manufacturing.

POTENTIALLY HAZARDOUS

Potentially hazardous food products that require a license or permitted facility (and cannot be made in a domestic kitchen) include:

a. Canned vegetables.

b. Low (or no) sugar jams, jellies and preserves.

c. Pickled vegetables and eggs.

d. Vegetable butters (sweet potato, pumpkin, etc.).

e. Salsas and chow chows.

f. Sauces and dressings.

g. Garlic (or other herbs and spices) in oil.

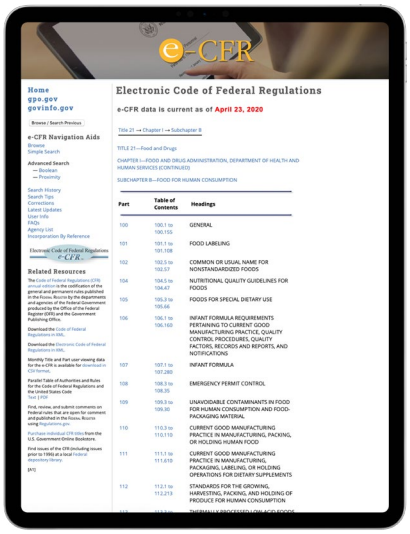
h. Products that contain meat or poultry.

i. Dairy or egg products, except as an ingredient in a non-potentially hazardous baked good or candy.

j. Any food that must be refrigerated and/or frozen.

If you are unsure if your product or specific recipe qualifies as non-potentially hazardous, the contacts at the end of this document may be able to help.

5. CURRENT GOOD MANUFACTURING PRACTICES



The regulation allowing non-potentially hazardous foods to be manufactured in a home or other non-permitted kitchen maintains the requirement for foods to be manufactured using current Good Manufacturing Practices (cGMPs) as defined by FDA in 21 CFR part 117. The complete up-to-date regulation on cGMPs can be found online at ecfr.gov (select Title 21 – Food and Drugs, and then click on parts [100-169]). The items discussed below address the criteria from the cGMPS that are most relevant to foods manufactured in a domestic kitchen.

This list is not all-encompassing; for more information regarding the full list of cGMP regulations, please consult the FDA CFR Title 21, Chapter I, Subchapter B, Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.

a. Disease Control

i. Any person working in the food production area who has an illness, open wound or any other abnormal source of microbial contamination cannot work in any areas associated with food contact. However, if a wound is easily covered by an impermeable cover and a glove can be worn over the cover, the person may continue to work in operations.

b. Cleanliness

i. Any person working in direct contact with food, food-contact surfaces and food-packaging materials must conform to hygienic practices.

ii. All persons must wash their hands thoroughly in an adequate hand-washing sink before starting work, after each time away from the production area, and other times when hands may have become soiled or contaminated.

iii. Personal belongings must be stored in a room other than the kitchen or any production area. All persons must remove all unsecured jewelry and other objects that might fall into food, equipment or containers.

iv. When appropriate, all persons must wear hair nets, headbands, caps, beard covers or other effective hair restraints in an effective manner.

v. All persons must refrain from eating food, chewing gum, drinking beverages or using tobacco when conducting food production operations.

c. Facilities – (applicable to a domestic kitchen)

i. There must be an easily accessible restroom with a working toilet and hand-washing station. The restroom used by all persons working in food production must be kept clean in order to avoid any possible contamination of food, food-contact surface or food-packaging materials.

ii. Trash and waste must be stored and disposed of to minimize the development of odor, minimize the potential for pests, and protect against contamination of all food, food-contact surfaces and food-packaging materials.

d. Sanitary Operations

i. The kitchen, fixtures, countertops and any place where food is processed, packaged or stored must be maintained in a clean and sanitary condition.

ii. Cleaning and sanitizing of all utensils and equipment must be conducted in a manner that protects against transfer of allergens and contamination of food, food-contact surfaces or food-packaging materials.

iii. Pets should not be allowed in a home with a domestic kitchen at any time due to potential of foreign material contamination and safety concerns (e.g., hair, parasites, feces).

iv. Insects and pests must be adequately controlled. When necessary, adequate screening or other protection against pests in processing and storage areas must be in place.

e. Equipment and Utensils

i. All equipment must be designed and maintained in a condition that is easily cleaned and sanitized (i.e., no damaged surfaces, crevices or any surface that could harbor allergens or microorganisms).

ii. Food-contact surfaces and utensils must be made of corrosion resistant, non-absorbent and non-toxic materials.

f. Food Processing

i. Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and food-grade.

ii. Raw materials and other ingredients must be inspected and stored under conditions that will protect against allergen cross-contact and contamination, as well as prevent spoilage.

iii. Any processing steps must be performed in a manner that minimizes any potential contamination.

iv. Food must be protected from contaminants that may drip, drain or be drawn into the food.

g. Storage

i. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location that prevents any allergen cross-contamination.

ii. Storage and transportation of food must be under conditions that will protect against allergen cross-contamination and against all contamination of food, as well as against deterioration or spoilage of the food and the container and packaging.

6. RECORDKEEPING

Keeping records of where ingredients are purchased is an important aspect of food safety. If there is ever an issue with a specific ingredient used in a product, the processor may be required to recall their own products to avoid spreading illness. Identifying which product to recall is made much easier by maintaining effective records of all ingredients used in all products. A current product sales list including quantities sold may also be of assistance should an incident occur.

7. LABELING REQUIREMENTS

All food items packaged must be properly labeled prior to sale. See figure below for an example of labeling on food packaging. The following at minimum must be present on all food packaging:

a. The name, street address, city, state and ZIP code of the manufacturer.

b. An accurate statement of the net amount of food in the package in English and metric units (e.g., ounces and grams).

c. The common or usual name of the food.

d. The ingredients in the food in order of predominance by weight.

e. All known allergens in the product (refer to Definitions section for more information).

f. Lot dates or numbers shall be evident on each package or container of food for traceability purposes in the event an issue occurs that may require a market withdrawal of the food.

Additional advisory labeling may alert consumers that a product could unintentionally contain an allergen or advise consumers that the product may have come in contact with an allergen. This typically happens when products that do not contain allergen ingredients are processed in the same facility, or using the same equipment, as products that do contain allergens. These allergen statements do not protect the processor from using poor sanitation practices (i.e., poor cGMPs that may not remove allergens) or liability if a person has an allergic reaction to your product. These statements only warn consumers with severe allergies.

Examples of optional advisory statements include:

- May contain (allergen[s]).
- Made on equipment that also processes (allergen[s]).
- Made in a facility that also processes (allergen[s]).

No nutrient content claims (e.g., "sugar free"), health claim or other nutritional claim can be provided on the label, or in labeling or advertising. Nutritional facts panels can be included but are not required for products made and sold directly to consumers under these Tennessee regulations. If any health claims are made on the packaging, or the product is intended to be sold across state lines, there are added labeling and processing requirements by the FDA.

8. ADDITIONAL INFORMATION AND REFERENCES

If you need more information on processing and producing any food products, please do not hesitate to contact the University of Tennessee Institute of Agriculture's Department of Food Science.

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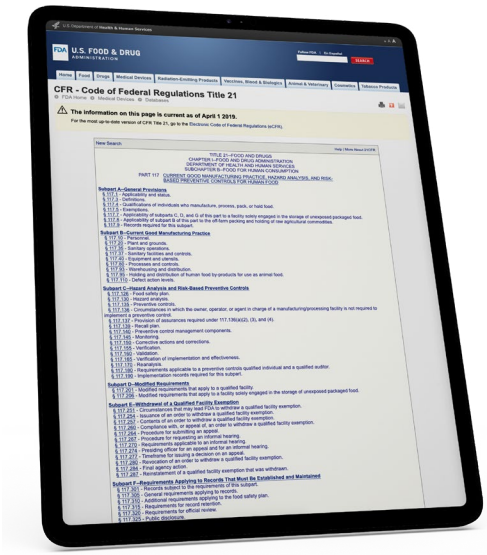

References for information given in this document:

FDA CFR Title 21, Chapter I, Subchapter B, Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=117

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