



Two Primary Categories of Processed Foods Regulated by the TN Department of Agriculture

- **Perishable:** Refrigerated or frozen temperatures are required.
- **Nonperishable:** Food items stored at ambient air temperatures above 41°F (shelf stable)

PERISHABLE processed foods require refrigerated temperatures to ensure food safety; less than 41°F for foods labeled “Keep Refrigerated” and foods maintained in frozen state for foods labeled as “Keep Frozen.” The low temperature slows or inhibits the growth of pathogenic bacteria making temperature controls and monitoring procedures very critical. During processing of perishable foods, exposure to temperatures above 41°F should be kept to a minimum.

In all NONPERISHABLE (Shelf Stable Products), the target pathogenic bacterium is *Clostridium botulinum*. This organism’s spores can withstand boiling temperatures for up to eight hours and reproduces by forming vegetative cells with spores. Spore destruction can only be accomplished by high heat (under pressure). An equilibrated pH of less than 4.6 will prevent the germination of spores to vegetative cells. Equilibrium pH is usually recorded after holding the product for at least 24 hours. The greater the density of the product, the longer it takes to achieve equilibrium. **The lower the pH at equilibrium, the greater the margin of safety, but you must balance the safety factor with palatability.**

Growth of vegetative cells of *C. botulinum* can be prevented by:

1. Equilibrating the pH at 4.6 or lower,
2. Keeping the water activity (A_w) at or below 0.85, or
3. Process for thermal destruction of spores.

Nonperishable (Shelf Stable) Processed Foods can be further classified into three categories:

1. **Formulated acid Foods** – foods that have a natural pH of 4.6 or less.
2. **Acidified Foods** – (21 CFR 114.3) a low-acid food to which suitable acidifying agent including, but not limited to vinegar, citric acid, or natural acid foods, such as tomato juice or lemon juice are added to adjust the pH to a safe level. An equilibrated pH of 4.6 or lower is considered a safe level. A few examples of acidified foods are: relishes, fresh-packed pickles, chow-chow and salsa.
3. **Low-Acid Foods** – a food to which high temperature processing is required to ensure food safety. The low-acid food is containerized and heat treated under pressure for a specified period of time. This is commonly known as pressure cooking and involves products such as green beans, corn, spinach, turnip greens, some vegetable soups, meats and fish.

Equipment and documentation required based on the product classifications:

1. **Formulated acid food processing and acidified food processing** requires the following:
 - a. pH Meter
 - b. Certified Thermometer
 - c. Processing Record Log (each lot)
 - d. Processed under the authority of an individual who has successfully completed the “Better Process Control School.”
 - e. Have schedule process for all products reviewed and approved by processing authority.

- f. All schedule processes must be filed with FDA for interstate and intrastate commerce submitting a copy of that confirmation letter to the Tennessee Department of Agriculture.

2. **Low-acid Food processing*** requires the following:

- a. Retorts properly equipped as required by the Code of Federal Regulations.
- b. Processing record log (each lot)
- c. Processed under the authority of an individual who has successfully completed the “Better Process Control School.”
- d. Calibrate “able” Thermometer
- e. Have schedule process for all products established by a process authority, including heat transfer test for specific products, containers, retorts and sizes, submitted to FDA, submitting a copy of that confirmation letter to the Tennessee Department of Agriculture.

*Low-acid canned foods are seldom commercially processed on a small scale because of the expense involved in equipment and professional assistance as required by the Code of Federal Regulations 21 CFR 113. All retorts must be approved through a processing authority that conducts the heat transfer test specific for a single retort for each product, container size and type.

Acidified and Low-acid Foods – Product Classifications and Scheduled Processes:

Acidified and low-acid food processors fall under specific regulations, Low-acid Canned Food (LACF) and Acidified Regulations 21 CFR 108, 113 & 114. Facilities that manufacture these products are required to have each product classified and its process approved by a processing authority. Classification of these products is accomplished by registering with the FDA using form FDA 2541 Food Canning Establishment Registration as well as file the schedule process form FDA 2541d Food Process Filing for Low-Acid Retorted Method or Food Process Filing for Acidified FDA 2541e, Food Process Filing for Water Activity/Formulation Control Method FDA 2541f and Food Process Filing for Low-acid Aseptic Systems FDA 2541g as are applicable. FDA requires a separate process filing form for each acidified and low-acid canned food, each specific product formulation or style, and each container type or size. A firm must re-file a schedule process if any changes are made to the process or if the firm relocates. For more information, please visit the following FDA website regarding registration and process filing:

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm>

Food that is exempt from the requirements of 21 CFR 114:

- Carbonated Beverages
- Jams
- Jellies
- Preserves
- Fruit Spreads and Batters
- Acid Foods¹
- Condiment Sauces
- Fermented Foods Preserved by Microbial Fermentation, i.e. Sauerkraut or pickles
- Alcoholic Beverages
- Foods with less than 0.85 water activity (A_w)
- Foods stored, distributed and retailed under Refrigeration
- Standardized and Non-Standardized Food Dressings²

¹Products with natural or normal pH of 4.6 or below

²Products that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food

Brix of Jams, Jellies, Preserves and Fruit Spreads or Fruit Butters:

1. Jams, jellies or preserves – 21 CFR 150.140 require a Brix level of not less than 65% soluble solids.
2. Fruit Butters – 21 CFR 150.110 require a Brix level of not less than 43% soluble solids.

Product Labeling:

Prior to the manufacture of products, all packaged product labels are subject to review by the Tennessee Department of Agriculture as administrative procedures enjoin. We will advise of any problems found with the labels. However, it is important to communicate to the public that TDA does not hold the authority to grant label approval. This service is done as a courtesy. Food labeling guidance documents can be found at FDA's website:

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/default.htm>

Basic label requirement for food products should include: (for complete requirements, see the webpage above)

1. The name and address including the zip code of manufacture, packer or distributor.
2. The net quantity of contents must be expressed in weight, measure or numeric count (i.e. liquid in fluid measurement; solid in weight; mixture (solid and liquid) in weight).
3. Metric declaration in addition to the weight or fluid (i.e. Net Weight 16 oz. (454 g); Net 16 FL Oz. (473 ml).
4. The common or usual name of the product.
5. A list of the ingredients, in order of descending predominance by weight, with the sub-ingredients of each ingredient listed as is applicable.
6. A lot or product code is to be applied to all packaged foods by the food manufacturer or processor at the time of packaging enabling tracing the product back to the product date, location and related information.

Bioterrorism Act of 2002: Designed to protect the United States from bioterrorism, the Public Health Security and Bioterrorism Preparedness and Response Act, commonly known as **The Bioterrorism Act of 2002** was created. The purpose of registration is to provide FDA with sufficient and reliable information about food and feed facilities. If you are an owner or operator of a domestic facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the U.S., you must register with FDA, unless exempt under 21 CFR 1.226 from the requirements to register. You must register your facility whether or not the food from the facility enters interstate commerce. For additional information regarding registration, check out the related FDA websites below.

The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year, and provides FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

- Created, caused, or was otherwise responsible for such reasonable probability; or
- Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>

Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition) November 2014

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>

Food Safety is everyone's responsibility!