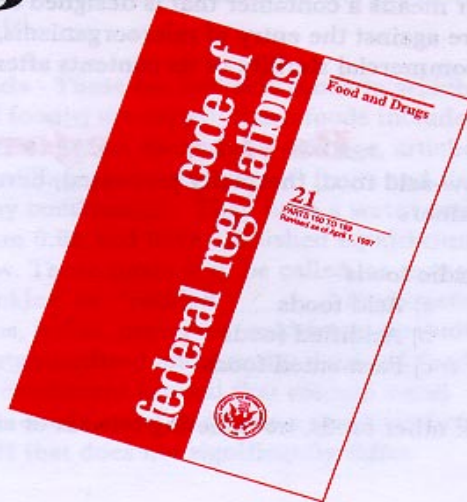


How Will Your Food Be Regulated?



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As you to prepare to enter the food business, you need to be aware of a few basic principles before making a total commitment. In UT Extension PB1399, **Getting Started In A Food Manufacturing Business In Tennessee**, the obstacles are defined with regard to the mechanisms of Good Manufacturing Practices (GMPs), labeling, legal aspects, types of permits, etc. However, the **Federal Code of Regulations** divides different foods into categories or classes, and they are regulated differently by the state and federal governments.

Foods are essentially differentiated by the amount of acid present, added and/or water activity (a_w) and whether the food is in a hermetically sealed container. A hermetically sealed container means a container that is designed and intended to be secure against the entry of microorganisms, thereby maintaining the commercial sterility of its contents after processing.

Basic Categories:

1. Low-acid food, thermally processed, hermetically-sealed containers
2. Acidic foods
 - a) Acid foods
 - b) Acidified foods
 - c) Fermented foods
3. All other foods, not meeting criteria of above classifications

Definitions:

1. *Low-acid, thermally processed, packaged in hermetically sealed containers.*

Any food, other than alcoholic beverages, with a finished pH greater than 4.6 and a water activity (a_w) greater than 0.85.

Exception:

Note: Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are **not** classified as low-acid foods.

Thermally-processed means the application of heat to food, either before or after sealing in hermetically sealed containers, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.

2. *Acidic foods:*

- A. **Acid foods** - These are foods with a natural pH of 4.6 or less (most fruits).
- B. **Acidified foods** - These are low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to: beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits and fish, singly or in any combination. They have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled _____." Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) 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, and foods that are stored, distributed and retailed under refrigeration are excluded from coverage of this part.

- C. **Fermented foods** - Fermented foods are produced through a process that increases the acid level, or lowers the pH, by taking advantage of the action of specific microorganisms. This is often referred to as a pickling process. Pickled foods should have a pH of 4.6 or less.

Fermented foods may be classified into products that essentially undergo an acidic, alcoholic or enzymatic fermentation. Important fermented products include fermented milks, most cheeses, fermented sausages, fermented vegetables and vinegars. Different microorganisms are utilized in the different food products to produce several different acids. It is these acids and the byproducts produced through the metabolism of these microorganisms that produce the preservation effect (i.e., acid) and the unique flavor and texture of fermented foods. It is also the presence of the naturally made acids that makes the food safer with a pH below 4.6.

3. *Other foods*

This includes any food that does not meet the above criteria, (i.e., bakery items, meats, fish, poultry, etc.). The above descriptions of the various food categories does not include products that are regulated by the USDA (i.e., meat and poultry).

In each of the above classifications, federal and state agencies regulate the food under different sets of regulations.

The following table illustrates the relationships between pH, water activity and current low-acid and acidified regulations. The table indicates whether a product is a low-acid or an acidified food and therefore must meet the

registration and process filing requirements of FDA. To use the table, determine the finished equilibrium pH and water activity (a_w) of the product. It is the relationship between pH and water activity that defines a product as low-acid or acidified. For example, if a food product has a pH less than or equal to 4.6 **and** water activity of 0.85 or below, it would **not** be covered by the low-acid regulations **nor** the acidified regulations. Thus, the firm would **not** be required to file scheduled process information for that product.

Relationship Between Ph, Water Activity and Low-acid or Acidified Regulations

Final Equilibrium pH	Water Activity (a_w)	Registration and Process Filing Required as:	
		Low Acid* (21CFR108.35/113)	Acidified** (21CFR108.25/114)
≤ 4.5	≤ 0.85	No	No
≤ 4.5	> 0.85	No	Yes
4.6	≤ 0.85	No	No
4.6	> 0.85	No	Yes
≥ 4.7	≤ 0.85	No	No
≥ 4.7	> 0.85	Yes	No

< less than

≤ less than or equal to

> greater than

≥ greater than or equal to

* A **yes** under this column defines the product as **low-acid**, subject to the requirements of 21 CFR, Parts 108.35 and 113, and means that the establishment must register the processing plant and file schedule process information for the low-acid product.

** A **yes** under this column defines the product as **acidified**, subject to the requirements of 21 CFR, Parts 108.25 and 114, and means that the establishment must register the processing plant and file schedule process information for the acidified product.

Note: This table does not apply to foods which are naturally or normally acid, as defined in the preceding paragraphs.

Reference: "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods," Department of Health and Human Services, Public Health Services, Food and Drug Administration, 1984.

pH:

The acid content of the food is one of the key elements in determining the category under which your food will be regulated. The strength of the acid is measured in terms of pH. Therefore, you should understand the meaning of pH and its significance in foods. pH is a measurement of acidity and is reported on a scale of 1.0 - 14.0, with neutral being 7.0 (meaning this is neither acid or basic). Any pH number below 7.0 means the product is on the acid side of the pH scale; a number above 7.0 means it is on the basic side. Very few foods have a pH of 7.0 or greater. The vast majority of foods have a pH range of approximately 2.5 - 6.0.

Since most foods have a pH below 7.0, this would indicate they are all acidic in nature. This, however, is not the case. In food science, we have drawn the line between “low-acid’ food and “acid” food at a pH of 4.6. “Low-acid” foods have a finished equilibrium greater than 4.6. These include foods such as meat, poultry, seafood, milk and fresh vegetables (except for tomatoes). “Acid” foods have a pH of 4.6 or lower. These include foods like jams and jellies, bar-b-que sauces, most salad dressings and most all fruits. The reason the pH of 4.6 is the key indicator is because most of the food-borne pathogenic microorganisms will not readily grow in a food that is high in acid or that has a pH of 4.6 or less.

Water activity (a_w):

Just like other animals, microorganisms have a specific demand for water. However, all water is “not created equal,” i.e., all water in a food is not available for a microorganism to use to sustain life and multiply. Therefore, the water activity (a_w) measurement tells you if there is enough available water for the microorganism to grow. A good example of a food that contains a lot of water, yet very little of this water is available to the microorganism for its growth and survival (low a_w), is a jam or jelly. Most bacteria will not grow or survive in jelly, because it has a low a_w due to the high sugar level. The sugar holds on tightly to the water so the microorganism cannot utilize it.

Regulatory Requirements:

1. Low-acid, thermally processed, hermetically sealed containers

In addition to the current Good Manufacturing Practices (GMPs), the processor must comply with several other criteria to meet the Code of Federal Regulations.

Operators of processing systems shall be under the operating supervision of a person who has attended a school approved by the FDA for the specific purpose of training supervisors and operators on the low-acid canned foods and/or acidified foods GMPs.

Equipment such as temperature recording devices, thermometers, pressure gauges, etc. must meet specific requirements. These requirements are set forth in 21CFR11340 (Code of Federal Regulations), Title 21, Section 113.4. The process used to make this product safe is referred to in the CFR as the “scheduled” process and this scheduled process must be filed with the FDA. This process must be established and documented by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers (See 21CFR113.83). Copies of the Code of Federal Regulations (CFR) parts 100-199 are for sale by the U.S. Government Printing Office, Superintendent of Documents, Mail Stop: SSOP, Washington, DC 20402-9328.

Specific processing records must also be maintained throughout the actual processing of the food (See 21 CFR113.100 Title 21).

2. Acidic foods

A. Acid foods

The regulation set forth for these foods are essentially the current Good Manufacturing Practices (GMPs). These are outlined in “Getting Started In A Food Manufacturing Business In Tennessee” (See UT Extension PB1399).

B. Acidified foods

Most of the requirements set for low-acid, hermetically-sealed containers also apply to acidified foods. Consequently, supervisory personnel need to attend an FDA-approved training school. The scheduled process must be set up by a qualified person and filed with FDA. Certain operating records must be maintained, and periodic reports filed with the FDA (See 21CFR114).

C. Fermented foods

Naturally fermented products are not considered as acidified foods. A naturally fermented product is one which:

- a. has been salted or in a brine solution, and
- b. has been allowed to ferment for one or more weeks in covered containers, and
- c. The product has reached a pH of 4.6 or below at the end of the fermentation period without the use of any added acid.

The growth of microorganisms and their enzymes in the product are responsible for the biochemical changes which occur during food fermentation, including the lowering of the pH to 4.6 or below. This is often referred to as a lactic acid fermentation. Sauerkraut, pickled cucumbers, cauliflower and dill pickles are examples of naturally fermented products.

Foods which are purported to have been “fermented” and have a pH after fermentation of greater than 4.6 and water activity is greater than 0.85 are low-acid foods. If acid is added before or after fermentation, in an amount sufficient to reduce the pH to 4.6 or below, the product is an acidified food. Fermented meat is regulated by the USDA.



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