

Tennessee Food Entrepreneurship Series

Manufacturing Acidified Foods in Tennessee

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What are acidified foods?

Regulatory agencies categorize foods by their pH, which is a measurement taken with a pH meter that describes how alkaline or acidic a substance is. The pH scale ranges from 0 (the most acid) to 14 (the most alkaline), with 7 considered neutral. Most foods have pH values in the acid range from around 2 to 6.5.

Foods are categorized as acid, low-acid or acidified based on the natural acidity of the product. Acid foods are foods with a pH at or below 4.6. Low-acid foods are foods with a pH above 4.6. Acidified foods are low-acid foods that have food grade organic acids or other acidic foods added to produce a final equilibrium pH at or below 4.6.

Some examples of acidified foods are pickles, chow chows, corn relishes and salsas.

Why is it important to have an equilibrium pH at or below 4.6 for acidified foods?

The pH value of 4.6 was selected as a limiting factor to control the growth of the bacterium, *Clostridium botulinum*. This organism will grow in canned or vacuum packaged products and produces a very deadly neurotoxin that causes possible paralysis and death if not treated. However, *C. botulinum* cannot grow at a pH of 4.6 or lower, and if the bacterium cannot grow, it can't produce the neurotoxin. A form of *C. botulinum* also is very heat-resistant and is not completely inactivated by processing at temperatures below 212 F. Properly acidifying low-acid foods requires a great deal of attention, which is the primary reason that specific federal regulations were implemented for acidified foods.

What regulations apply to acidified foods?

If you are making a U.S. Food and Drug Administration-regulated product (any food product that contains less than 2 percent cooked meat or poultry), you should become familiar with the regulations described in the Code of Federal Regulations Title 21 Part 110. These regulations are known as Good Manufacturing Practices (GMPs) that all food manufacturers must adhere to. A copy of these regulations can be accessed through the UT Department of Food Science and Technology's Extension website (<https://ag.tennessee.edu/foodscience/Pages/default.aspx>).

What initial steps should I take to begin manufacturing acidified foods?

There are several items on the "To-Do List" when you are getting started on the path to manufacturing acidified foods.





- 1) Complete the Better Process Control School program.

The first step is to complete the Better Process Control School program. Traditionally, this program is offered in the fall by the University of Tennessee and throughout the year at other land-grant universities. Please contact the UT Department of Food Science and Technology for a current list of courses.

- 2) Find a commercial facility for manufacturing your product.

- 3) Contact the Tennessee Department of Agriculture's Regulatory Services Division to review and approve any remodeling or new construction.

You also should find an appropriate facility in which to manufacture your acidified foods. This facility must meet all the requirements as outlined in the GMPs and must be approved by the TDA Regulatory Services Division. If you are constructing or remodeling a facility, the facility plans and specifications must be reviewed and approved by the TDA prior to beginning construction. You should contact Ronald Murphy with the TDA at ronald.murphy@TN.gov or 615-837-5153 for information on having your plans reviewed.

- 4) Register your facility with the FDA by completing and submitting Form 2541.

Once you have located an appropriate commercial facility, you should register this facility with the FDA for products regulated by this agency by filling out Form 2541, which can be accessed online at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076778.pdf>. Submission of the form will trigger the FDA to issue your facility a Food Canning Establishment number, or FCE, which will be used on other FDA forms.

- 5) Register your facility to be in compliance with the Bioterrorism Act.

The Public Health Security and Bioterrorism Preparedness Response Act of 2002 also requires food manufacturing facilities to register with the FDA. This registration is separate from Form 2541 and may be completed online at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm>.

- 6) Work with a process authority to develop a scheduled process and determine any critical factors for your product.

The regulations for acidified foods state that you must work with a process authority to determine an appropriate scheduled process for your product(s). This person has the training and experience necessary to determine the appropriate processing conditions and critical factors needed to produce a commercially sterile product as required by the acidified food regulations. Dr. Faith Critzer, a UT Extension food safety specialist, serves as a process authority for acidified foods and will work with you to evaluate your product and processing conditions to determine the appropriate process and any critical factors that are pertinent to produce a wholesome acidified food. You may contact Critzer at faithc@utk.edu or 865-974-7274.

- 7) Submit Form 2541a for each product.

Once you have determined the appropriate scheduled process for your product, you should fill out FDA Form 2541a. A separate form should be completed and submitted to the FDA for each product that you manufacture. For instance, if you produce a hot and mild salsa, you would need to submit two separate 2541a forms. Form 2541a can be accessed at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076784.pdf>.

- 8) Obtain a food manufacturers license through the TDA Regulatory Services Division.

Now that you have taken all the appropriate steps to manufacture acidified foods, you are almost finished with the process. Next, you need to obtain a food manufacturers license through the TDA. Again, contact Ronald Murphy at ronald.murphy@TN.gov or 615-837-5153 to schedule an inspection of your facility.

What processing requirements must I adhere to?

Acidified food manufacturers must keep records documenting that they have adhered to the scheduled process submitted to the FDA (Form 2541a). At a minimum, these records need to indicate that (1) The scheduled process was achieved by recording the processing time and temperature, (2) The equilibrium pH of the product was at or below that indicated on the scheduled process within 24 hours of processing, and (3) An evaluation of container integrity is completed, typically by checking for a vacuum. Records should be maintained and kept up to date for each lot of food, be accurate and be filed so that they can be accessed easily. If other critical factors are described in the scheduled process, such as minimum initial temperature, records need to be kept in the fashion described above.

What instrument do I use to determine pH?

Most acidified food manufacturers will measure pH using a meter that determines pH with the potentiometric method. This method involves immersing a pH probe containing two electrodes connected to the pH meter in a food. The pH is determined by measuring the difference in potential between the two electrodes. A pH meter is a very important piece of equipment that you will use to evaluate your finished product when manufacturing acidified foods.

There are several types of pH meters on the market. They can range in price from \$100 to more than \$1,000, so trying to select one for your operation may be very confusing. The primary factors that contribute to the cost of pH meters are resolution, accuracy and temperature compensation. Resolution is an indication of how precise an instrument can read. The acidified food regulations require a resolution of 0.05 pH units, but a higher resolution will give you a more precise value. Typically, a resolution of 0.01 is desirable for processing acidified foods. Accuracy is a reflection of how close a reading is to the "true" pH value. Usually, lower-cost meters will have an accuracy of ± 0.2 pH units. For example, if the pH meter read 4.3, the actual pH of the product could be anywhere from 4.1 to 4.5. This range in accuracy may be a problem if the pH of your product reaches the legal limit of 4.6 or if the equilibrium pH rises above what is described in your scheduled process. Generally, an accuracy of ± 0.02 pH units is desirable when processing acidified foods. Temperature compensation should be automatic for the meter you select. pH measurement is standardized at a temperature of 25 C (77 F). Temperatures above or below 25 C (77 F) will impact the sensitivity of your electrode. pH meters with temperature compensation will correct for this impact to sensitivity based on sample temperature.

How do I test the pH of a food sample?

Calibrate the pH meter. Calibrating the pH meter should be done at minimum once per day or once per shift. It is important to follow the manufacturer's instructions for calibration. A typical calibration procedure uses standardized buffer solutions of pH 4.01 and 7.0. You should use freshly dispensed buffer for calibration since the pH of buffer solutions exposed to air will vary due to the absorption of carbon dioxide and evaporation. You also will need to rinse the probe with deionized water and blot it dry carefully with a lint-free tissue between standards. It is important not to rub the probe when drying, as this may damage the electrode membrane or create a static charge that can impact accuracy. Also, glass pH probes break easily. Records should be maintained to demonstrate that the pH meter has been calibrated appropriately.

Preparing food samples for pH testing. Acidified foods come in all shapes and sizes. Some foods consist of a liquid and solid portion that can differ slightly in acidity. Others are more homogenous and semisolid in nature. Here are some guidelines to follow when preparing your products for pH measurement:

1) Liquid and solid mixtures. These products can be prepared in two different ways:

- Method 1
 - Blend the entire container to a homogenous paste, equilibrate to room temperature (77 F) and record the equilibrium pH.



- Method 2
 - Drain the contents of a container for two minutes on a U.S. standard No. 8 sieve (purchased at a scientific supply store) inclined at a 17- to 20-degree angle. Record the weight of the liquid and solid portions and retain each portion separately.
 - Liquids containing oil may cause fouling of the electrode. If fouling occurs, separate the oil and water layers with a separatory funnel and retain the aqueous or water layer. The oil layer may be discarded. Adjust the temperature of the aqueous layer to 77 F and determine its pH.
 - Remove the drained solids from the sieve, blend to a uniform paste, adjust the temperature of the paste to 77 F and determine its pH.
 - Mix aliquots of solid and liquid fractions in the same ratio as found in the original container and blend to a uniform consistency. Adjust the temperature of the blend to 77 F and determine the equilibrium pH.

2) Marinated oil products.

- Separate the oil from the solid product. Blend the solid in a blender to a paste consistency; you may need to add a small amount of distilled water to some samples to facilitate the blending. A small amount of distilled water will not alter the pH of most food products. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH of the solid at 77 F.

3) Semisolid products.

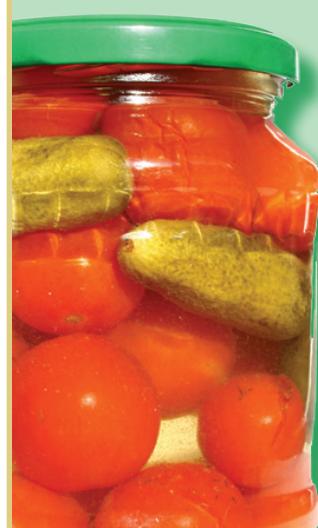
- Food products of a semisolid consistency may be blended to a paste. If more fluidity is required, 10 to 20 milliliters of distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 77 F and determine its pH.

Using the pH meter.

- After the meter has been calibrated, rinse the probe with distilled water and blot dry with a lint-free tissue paper.
- Immerse the sensing tip of the electrode for at least one minute to allow the meter to stabilize and record the pH to the nearest 0.05 pH unit.
- Rinse the probe, blot dry and repeat the measurement on a fresh sample.
- These two measurements should agree within the accuracy limits of the meter and should be maintained in product records.

Cleaning a dirty electrode. Occasionally, electrodes will become fouled with fats or other food components that will impact the meter's ability to report pH. Fouling is most likely the cause if the meter is slow to respond or the pH readings are erratic. First, rinse the electrode in tap water for several minutes to help flush away any food residue.

- Check the sensing portion of the probe to determine if there is any visible debris; if so, remove it carefully with a lint-free tissue.
- Immerse the probe in a 0.1 molar sodium hydroxide solution (0.1M NaOH) for one minute and transfer the probe to a 0.1 molar hydrochloric acid solution (0.1M HCl). Both of these solutions can be purchased through scientific supply companies at these concentrations.
- Rinse the probe tip for a minute with tap water.
- If visible oil remains, wipe the probe with a lint-free tissue soaked in acetone.
- Rinse the probe tip with distilled or deionized water for a minute.
- Calibrate the probe to ensure that the electrode is reading properly.



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