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SP747-B Manufacturing Formulated Acid Foods in Tennessee

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What are formulated acid 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. Formulated acid foods are normally acid foods but have a small amount of low-acid ingredients added. Regulatory agencies require formulated acid foods to have a final pH at or below 4.6. The foods should not contain greater than 10 percent by weight of low-acid ingredients. At these levels, the low-acid ingredients do not significantly change the pH of the acid ingredients.

Some examples of formulated acid foods are dressings, marinades and barbecue sauces.

Why is it important to have a pH at or below 4.6 for formulated acid 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 formulated acid 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 formulated acid foods?
There are several items on the “To-Do List” when you are getting started on the path to manufacturing formulated acid foods.
1) Find a commercial facility for manufacturing your product.

First, you should find an appropriate facility to manufacture your formulated acid 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.

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

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

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

4) Work with a food safety expert to develop a manufacturing process and determine any critical factors for your product.

Dr. Faith Critzer, a UT Extension food safety specialist, assists formulated acid food manufacturers by reviewing their processing steps; evaluating product attributes, such as pH; and developing minimum processing parameters that should be followed to produce a commercially sterile product. You may contact Critzer at faithc@utk.edu or 865-974-7274.

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

Now that you have taken all the appropriate steps to manufacture formulated acid 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.

**Intermediate Acid Foods**

Some foods, such as tomatoes and tropical fruits, will predominantly have an acid pH, but may vary to a point where the pH rises above 4.6. Bananas, pineapple, papayas, melons and honey are all examples of intermediate acid foods. If your formula calls for an intermediate acid food, it is important to always check the pH of that ingredient to ensure that it is at or below 4.6.

**Are there any important product attributes that should be recorded?**

Records indicating the finished equilibrium product pH, processing conditions and evaluation of container integrity should be maintained for each batch of formulated acid food manufactured. Other records, such as ingredient source and lot code, may help troubleshoot problems with spoilage. Records should be maintained and kept up to date for each batch of food, be accurate and be filed so that they can be accessed easily.

**What instrument do I use to determine pH?**

Most formulated acid 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 formulated acid 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 the pH meters are resolution, accuracy and temperature.
compensation. Resolution is an indication of how precise an instrument is. The least expensive pH meters will have a resolution of 0.1, but a higher resolution will give you a more precise value. Typically, a resolution of 0.01 is desirable for processing formulated acid 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 formulated acid 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 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.* Formulated acid 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
     o Blend the entire container to a homogenous paste, equilibrate to room temperature (77 F) and record the pH.
   - Method 2
     o 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.
     o 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.
     o 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.
     o 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.