Step-by-Step Guidelines for Processing, Manufacturing, and Regulatory Approval of Acidified Foods in Georgia

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TO DO BEFORE GETTING STARTED WITH MANUFACTURING ACIDIFIED FOODS IN GEORGIA

- ☐ Attend an approved Better Process Control School to earn your process certification.
- ☐ Find a suitable commercial facility for manufacturing your product; have it inspected and licensed by the Georgia Department of Agriculture Manufactured Foods Division.
- ☐ Register your facility with the FDA by completing and submitting Form 2541.
- ☐ Develop a scheduled process approved by an FDA-recognized process authority, and determine any critical factors to assure the safety of your product.
- ☐ Submit Form 2541a for each acidified product to FDA.
- ☐ Establish an effective record keeping system to document your processes and to provide a basis for traceback in the event of a recall; keep these records up-to-date and complete.

The intent of this bulletin is to provide basic scientific principles and regulatory requirements for processing, manufacturing, and regulatory approval of acidified foods. This guide contains step-by-step information on how to get started and includes forms and links with important contact information to help you along the way to becoming a licensed acidified food processor/manufacturer. Failure to adhere to these requirements may lead to the foods being deemed adulterated and subject to a state or federal recall.

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INTRODUCTION

Acidified or "pickled" foods is one of the United States' largest food manufacturing sectors. Acidified foods are popular among American food entrepreneurs and processors interested in manufacturing and/or processing value-added food commodities. Acidified foods date back more than a thousand years as a way to produce high quality and safer food products. However, several foodborne illness outbreaks in recent years[1,2,3] have resulted in several high profile and large-scale food recalls[4,5]. Therefore commercial acidified food processors must be vigilant about ensuring the safety of their products. An acidified food can pose a risk of botulism if the pH and other food safety factors are not carefully controlled during processing to prevent the germination of *Clostridium botulinum* spores and their subsequent growth and toxin formation.

The vegetative cells of some spoilage bacteria, yeasts, and molds also can grow in an acidic environment and cause the pH of the food to increase, providing an opportunity for *Clostridium botulinum* spores to germinate. To prevent occurrence of any health hazard, food processors must be in compliance with regulations established by the U.S. Food and Drug Administration (FDA) and state agriculture and health departments across the United States.

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[1] Besser, R.E., et al. 1993. An outbreak of diarrhea and hemolytic uremic syndrome from *Escherichia coli* 0157:H7 in fresh pressed apple cider. *JAMA 269*(17), 2217-2220. doi:10.1001/jama.1993.03500170047032

[2] Centers for Disease Control and Prevention. 1997. Outbreaks of *Escherichia coli* O157:H7 infection and cyptosporidiosis associated with drinking unpasteurized apple cider. *Morbidity and Mortality Weekly Report 46*(01), 4-8. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/00045558.htm

[3] Weagant, S.D., et al. 1994. Survival of *Escherichia coli* 0157:H7 in mayonnaise and mayonnaise-based sauces at room temperature. *Journal of Food Protection 57*(7), 629-631.

[4] Centers for Disease Control and Prevention. 1999. Outbreak of *Salmonella* Serotype Muenchen infections associated with unpasteurized orange juice. *Morbidity and Mortality Weekly Report 48*(27), 582-585. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4827a2.htm

[5] Centers for Disease Control and Prevention. 1996. Outbreak of *Escherichia coli* O157:H7 infections associated with drinking unpasteurized commercial apple juice. *Morbidity and Mortality Weekly Report 45*(44), 975. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/00044358.htm

The FDA has the responsibility under the Federal Food, Drug and Cosmetic Act to prevent the interstate distribution of food products that may be injurious to health or that are otherwise adulterated (as defined in section 402; 21 U.S.C. 342). Under the authority granted to the FDA (section 404; 21 U.S.C. 344), regulations require the registration of food processing establishments, filing of process information and other data, and maintenance of processing and production records for acidified foods in hermetically sealed containers (21 CFR 108.25(c) and 108.35(c)). These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit the FDA to verify that these procedures are being followed. Improperly processed acidified foods may present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum*. The spores of *Clostridium botulinum* must be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This can be accomplished with good manufacturing procedures and approved recipes, which must include proper verification and use of adequate heat processes and/or other means of preservation.

ACIDIFIED FOODS

The term ***acidified foods*** means low-acid foods to which acid(s) or acid food(s) are added; to have a ***water activity*** (A_w) greater than 0.85 and a ***finished equilibrium pH*** of 4.6 or below within the time designated in the approved scheduled process.

Acidified foods include, but are not limited to:

- pickled beets, cocktail onions, and cherry peppers (normally pickled by the addition of acid);
- red bell peppers treated in an acid brine;
- some pears and tropical fruits that have a natural pH greater than 4.6 and are acidified to a pH of 4.6 or below;
- fermented green olives subjected to processes (such as lye treatment or washing with low acid foods) that raise the pH above 4.6, with subsequent addition of acid or acid foods to reduce the pH to 4.6 or below;
- tomato salsa, made from tomatoes with a pH of 4.6 or below and other low-acid ingredients, when the amount of low-acid ingredients is not a small amount and/or the resultant finished equilibrium pH differs significantly from that of the predominant acid or acid food; and
- cold-pack pickles that are subjected to the action of acid-producing microorganisms, but require the addition of acid or an acid food to achieve a pH of 4.6 or below.

After proper acidification, acidified foods must be heat processed to destroy the vegetative cells of pathogenic and spoilage microorganisms and to inactivate natural enzymes present in food that might affect color, flavor, or texture of the product. In some circumstances, some acidified food products can become discolored or darken due to natural enzymes reacting with oxygen to form brown pigments. Blanching may be the best way to avoid such discoloration of browning. Blanching is a processing step by which raw food products are immersed in hot water at 190-210 degrees F for several seconds.

Acidified foods in a sealed jar can be heat processed in a boiling water bath or by hot-fill-and-hold pasteurization. The processing time, temperature, and procedures necessary to safely preserve acidified foods are determined by factors such as the level of acidity (pH), size of food pieces (density), and percentage of salt. An FDA-recognized processing authority must review the product and processing to make the appropriate recommendations about time and temperature requirements. Processing temperatures higher than 185 degrees F (85 degrees C) could break down pectin in certain foods, or cause unnecessary softening of some acidified foods.

FOODS CONSIDERED "NOT ACIDIFIED" BY THE FDA

The FDA definition of acidified foods provides that carbonated beverages and foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of 21 CFR Part 114 (21 CFR 114.3(b)).

The following foods are **NOT** considered to be acidified:

- Naturally acid foods that have a pH of 4.6 or less.
- Standardized and non-standardized food dressings and condiment sauces that contain small amounts of low-acid food(s) and have a finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food.
- Alcoholic beverages.
- Carbonated beverages.
- Standardized jams, jellies, and preserves (21 CFR 150).
- Tomatoes and tomato products having a finished equilibrium pH less than 4.7.
- Foods that are NOT packaged in hermetically sealed containers.
- Any food prepared under the continuous inspection of the meat and poultry inspection program of the Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture under the Federal Meat Inspection Act and the Poultry Products Inspection Act.
- Foods that are stored, distributed, and retailed under refrigeration.
- Foods with water activity of 0.85 or below.
- Foods that are not thermally processed.

Because these foods are not recognized as acidified foods, commercial processors are not required to register their processing information for these products with the Food and Drug Administration.

CAUTION: During the preparation of acidified foods, insufficient acidification within the time designated in the scheduled process or inadequate quantity of the acid in the brine to overcome buffering capacity of the food, or failure of the acid to fully penetrate into the product due to the presence of alkaline compounds from peeling or other processing aids, and the peels, waxing, piece size or oil in the product, may cause the failure to achieve the final equilibrium pH value of 4.6 or below and may raise food safety concerns for the acidified food. Failure to attain a final equilibrium pH value of 4.6 or below may lead to the growth of foodborne pathogens and production of hazardous microbial toxins in the finished product.

Step-by-Step Guidelines for Processing, Formulation, and Manufacturing of Acidified Foods in Georgia

The procedures outlined below pertain to processors in the state of Georgia and may not be appropriate for processors in other states. Contact your local Cooperative Extension office or state Department of Agriculture for assistance.

STEP 1: CONTACT THE GEORGIA DEPARTMENT OF AGRICULTURE – FOOD SAFETY DIVISION

Contact the Georgia Department of Agriculture (GDA) Food Safety Division (Manufactured Food Section, MFS) at (404) 657-4801. You will need to provide a detailed description of the product, process, ingredients, and any other necessary information that GDA may require. A GDA-MFS representative may also inquire if you intend to use your own GDA-inspected and approved kitchen or processing facility, a shared kitchen, or a co-packer. For the approval of a new location, the GDA may require the processor to test the source water and ensure it is deemed potable. These test results must be provided to the GDA-MFS in a timely manner.

If you are building your own kitchen or food processing facility, the consultation visit will include an evaluation of the food preparation area to ensure that it meets all applicable health, food safety, construction, and sanitation requirements.

Prior to Facility Licensing:

- Contact your city/county Planning and Zoning Office and/or Business Development Office and work with them to obtain a Certificate of Occupancy and/or ***business license*** for your business.
- If you are using a private water source for your business operation, have your water sample collected and tested annually by the GDA for coliform bacteria and nitrates.
- For private sewage/septic, you will need to contact the local health department to ensure the septic system can handle the output from your operations.
- You will need to submit a ***business plan*** to ensure that your operation meets the basic regulatory requirements. Business plan reviews are required in order to determine whether the firm requires licensing from the GDA, if the firm's operations are within the scope of the GDA's regulations, and to ensure the facilities provided are adequate for the food that is being produced and/or sold on the premises.
- As a food processor, you must make sure that your product is labeled correctly and reviewed by the GDA. It is the firm's responsibility to ensure the label(s) on all food product(s) are accurate and meet the regulatory requirements. Review the GDA's Food Labeling brochure for advice on creating food labels, and refer to the FDA's Food Labeling Guide for additional guidance. A final review by GDA-MFD is required prior to offering products for sale in Georgia.
- Once you're ready, complete a GDA ***license application*** and submit it to the GDA. In addition to your license, you will need to complete secure and verifiable (S&V) documentation, otherwise referred to as "Verification of Lawful Presence." To meet this requirement, you will need to complete a notarized affidavit and provide at least one acceptable form of proof of citizenship/ immigration status.
- Once all your information has been submitted and reviewed, the Manufactured Foods Division (GDA-MFD) will have an inspector contact you to schedule the license inspection. Upon the time of your inspection, the inspector will want to examine all your new business information.

- To ensure timely licensing of your operation, be prepared to provide the inspector with a packet containing the license, S&V documentation, business plan, final product label(s), and payment for the annual license fee.

Manufacturing facilities are also required to register the business with the FDA. If this is a new business, you will have to create an online account and register with FDA. Be sure to save the information you are given at the end of your registration in a safe place, so you can access your online account.

Please visit: www.agr.georgia.gov/manufactured-foods.aspx for more detailed information.

STEP 2: CREATE A SCHEDULE PROCESS FOR YOUR PRODUCT

A critical part of manufacturing an acidified food is to make sure that the finished food product does not pose a public health hazard. Acidified food manufacturers must ensure that the acidified food is processed according to a scheduled process that is adequate to destroy the vegetative cells of microorganisms of public health significance. A ***schedule process*** must be designed, reviewed, and approved by a process authority to deliver a "commercially sterile" or "shelf-stable" food product. The schedule process is designed to describe the process and procedure for acidification, thermal processing, and packaging, in a manner that renders the finished product free of microorganisms of public health significance under non-refrigerated conditions of storage and distribution.

The cooking step (time and temperature) in making a food product is called a thermal process. A thermal process is established by understanding the food microbiology and processing method for the specific food that is canned. Food spoilage microorganisms are present throughout the environment, packaging containers, and ingredients. High temperature kills microorganisms present in food, and the hermetically sealed container prevents recontamination. Thermal processes are specific to food formulation, preparation, container, and thermal method used. The thermal resistance of the microorganism depends on the growth characteristic of the microorganism and on the nature of the food, that is, the acidity of the food or if it is whole, chopped, or pureed. A dense food such as meat will heat more slowly than, say, asparagus. Similarly, a mashed vegetable will heat more slowly than whole vegetables in a brine or broth. Food product heating data are collected by placing a temperature sensor in the product at the slowest heating (coldest) region.

Among other factors, the scheduled process may specify other critical factors that must be controlled to assure the manufacture of safe acidified foods. A scheduled process must be established by a qualified person or a competent process authority, with expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods. Scheduled processes must be followed during manufacture of the food, and critical factors must be monitored under the operating supervision of an individual who has attended and successfully completed a course and has become certified to supervise those operations.

Failure to control critical factors specified in the scheduled process (for example, maximum equilibrium pH, titratable acidity, preservatives, time and temperature for thermal processing, etc.) will be considered a deviation from the schedule process. The appropriate deviation must be properly documented at the time of occurrence, and the affected product must be set aside for evaluation by the processing authority. The product in question may be reprocessed or completely destroyed based on the recommendations of the processing authority or according to pre-planned corrective action as designed by the processing

authority. Products with low vacuum or improper seals shall be treated in a similar manner. Records of all departures from scheduled processes must be properly maintained in a separate file for three years.

STEP 3: GET YOUR PRODUCT TESTED FOR pH AND PRODUCT CLASSIFICATION

Prepare a test batch of your product, and get the product evaluated to determine if it meets minimum criteria for the acidified food product classification. The University of Georgia (UGA) Extension Food Science (EFS) provides a product classification form online to send with your product sample for product classification. Please provide detailed information about your product and processing information along with your processing facility information if you are using your own GDA-approved-and-inspected kitchen, a co-packer, or a shared kitchen facility to manufacture your product.

Please be advised that it is critical to have your product pH tested for an accurate pH determination before your product is classified. Please arrange to have your product shipped to UGA-EFS for timely action on your product classification.

Please provide all critical factors in your process, such as pH, storage, and distribution conditions as they relate to your product to your processing authority before the classification.

Information regarding the product recipe, processing methods, and other details are kept confidential unless otherwise stated. It is the responsibility of the processor(s) to provide as much detailed information to the processing authority in a timely manner for appropriate classification of the product. It is the responsibility of the processor or food manufacturer to make sure they have contacted the GDA and/or FDA regarding additional regulatory requirements relevant to their products and processes.

If the product is classified as ACID, the food processor is exempted from filing for a process approval and FDA schedule process (FDA Form 2541a). Skip to Step 6 below to continue setting up your processing procedures.

If it is determined that your product is classified as ACIDIFIED, please continue with the following steps.

STEP 4: ATTEND AN FDA-APPROVED BETTER PROCESS CONTROL SCHOOL

You must attend and pass an approved Better Process Control School (BPCS) before engaging in the commercial production of acidified foods. This is a requirement of both the Food and Drug Administration (FDA) per 21 CFR 114.10 and the Georgia Department of Agriculture (GDA). You will need to provide a copy of your certificate of successful completion of the Better Process Control School class to the GDA and UGA EFS, if you choose to use their services as your process authority.

The UGA Extension Food Science Outreach Program (EFS) offers a full, four-day BPCS in March and a two-and-a-half-day Acidified BPCS in November each year. Consult the EFS calendar at http://efsonline.uga.edu for the dates and location where the workshops will be held.

Other BPCS workshops are held at different dates around the country. Search Google for "BPCS" to find one that fits your needs. The certification is accepted nationwide, and at the present time, does not expire.

STEP 5: SUBMIT THE RECIPE AND FINISHED PRODUCT TO AN FDA-RECOGNIZED PROCESS AUTHORITY FOR REVIEW AND APPROVAL

If your product is classified as ***acidified,*** you will require the assistance of a recognized ***process authority*** (a person with expert knowledge in the acidification and processing of acidified foods) to approve the safety of your recipe and develop a scheduled process (Form 2541a) to submit to the FDA.

Process approval and product classification require a detailed evaluation of how a food product is made, including all of the steps of preparation, ingredients, and packaging. The procedures for a UGA Process Approval are outlined below. A fillable PDF of the UGA form is available on the EFS website—go to http://efsonline.uga.edu and click on the "Process Approval" link.

After the submission of a completed process approval form, the process authority will evaluate product formulation, thermal processing criteria (time and temperature to achieve maximum lethality to eliminate microorganisms of public health significance in the product), preservatives, percentage of raw ingredients, acidification of the low-acid ingredients, and the final equilibrium pH of the finished product. Thermal processes or product cooking temperature are specific to food formulation, preparation, container, and thermal method used.

The ***hot-fill-and-hold processing method*** can be used for foods that are acid or acidified. All ingredients are thermally processed in a steam kettle, then transferred to a clean container, sealed, and held for a pre-determined time. Reaching a minimum temperature of 185 degrees F is critical for the commercial sterility of the container and for vacuum formation within the container, resulting in a hermetically sealed container.

As defined in the Code of Federal Regulations (21 CFR 113.83 and 113.89), "A processing authority is a person who has expert knowledge of thermal processing requirements for low-acid foods packaged in hermetically sealed containers, or has expert knowledge in the acidification and processing of acidified foods."

The UGA-EFS process approval form has been developed to help the acidified food processor file its own 2541a form with minimal input from a processing authority.

It is the responsibility of the food processor to ensure that he or she has filed 2541a form with FDA correctly and in a timely manner. A Georgia food manufacturer must ensure that they have met GDA and FDA requirements for the food facility registration and schedule process filing before actual commercial production and/or product sale in the market place.

CAUTION: A schedule process filing and/or food facility registration does not ensure that the product that you are manufacturing is "SAFE" for consumption. "Food product safety" is the sole responsibility of the food manufacturer/owner/processor.

STEP 6: DEVELOP AN ACCURATE RECORD KEEPING SYSTEM TO VERIFY AND VALIDATE ADHERENCE TO THE SCHEDULED PROCESS AND FOOD SAFETY PARAMETERS

Processors of any food item, not just acidified foods, must maintain records for the examination of all raw ingredients, packaging materials, and finished products, as well as of the suppliers' guarantees or certifications that verify compliance with GFA and FDA regulations and guidelines.

Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors to ensure a safe product, shall be maintained and shall contain sufficient additional information, such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.

All deviations from scheduled processes having a possible bearing on public health or the safety of the acidified food shall be noted, and the affected portion of the product identified. Deviation shall also be recorded on a separate log identifying the appropriate data, delineating the problems, the action taken to rectify them, and the disposition of the portion of the product involved.

Keep all of your records (licenses, certifications, process authority reviews, FDA forms, etc.) together in one place, preferably in a binder. Requirements for retaining records are identified in 21 CFR 114.100. You may receive a visit from FDA or GDA inspectors at any time to observe your process, inspect your facility, and review processing records. Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

Copies of all records shall be retained at the processing plant or other reasonably accessible location for a period of three years from the date of manufacture.

FDA regulations (21 CFR Parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations 21 CFR 108.25(c) or 21 CFR 108.35(c).

These records must be made available to FDA or GDA inspectors upon request. Firms are also required to document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, 114.100(c)); report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d), 108.35(d)-(e)); and develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e), 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods), 114.80(b) (acidified foods)).

The records of processing information MUST be periodically reviewed to verify fulfillment of the requirements in 21 CFR Parts 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

Additionally, acidified food processors are required to develop a recall plan, logs for monitoring critical control points (i.e., temperatures, pH, cook times, batch numbers), logs for recording pH meter and thermometer calibrations, a deviation log, container closure log, corrective action logs, and a method for recording distribution to the first point of sale for all products sold.

STEP 7: CREATE A LABEL FOR YOUR PRODUCTS

See the FDA *Food Labeling Guide* for developing your label. Your finished label must be reviewed by the GDA Manufactured Foods Division (MSD) before selling your product.

All product labels should be critiqued by designated processing plant personnel to determine that all parts of the label are accurate prior to submission to GDA-MFD for review.

At a minimum, the basic label requirement for a packaged food product must include:

- ☐ the name and address including the zip code of manufacturer, packer, or distributor
- ☐ the common or usual name of the product
- ☐ the net weight of the product in definite units;
  - ► if liquid, in liquid measure
  - ► if solid, in terms of weight (ounces/pounds or grams/kilograms)
  - ► if a mixture (solid and liquid), in terms of weight
- ☐ the date of process
- ☐ the use-by date
- ☐ the lot or batch code
- ☐ the declaration of contents of a package must be listed on the bottom 30 percent of the principal display panel
- ☐ the metric declaration must be listed on the label of food products. For example: Net Wt.16 oz (454 g.); Net. 16 Fl. Oz. (473 ml.)
- ☐ the common name of the product
- ☐ a list of ingredients and the common name of each ingredient in the order of predominance by weight. Under certain conditions, the following are necessary:
  - ► optional ingredients
  - ► dietary properties, if claimed
  - ► artificial ingredients, if used
  - ► preservatives identified in the ingredients statement
  - ► any imitation ingredient must be clearly designated
  - ► appropriate nutrition labeling, per NLEA requirements
- ☐ the allergen declaration after the ingredients statement

STEP 8: CREATE A BATCH OR LOT CODING SCHEME

A product code shall be applied to all packaged foods by the food manufacturer or processor at the time of packaging, which indicates information that would be critical in tracing the product back to the production date, location, and even to the source of ingredients (depending on how well they have been documented), as required in 21 CFR 114.80(b). Complete and effective documentation can reduce risk to your company in the event of a recall.

A food container coding scheme provides food manufacturers with a way to track food and isolate affected products in the event of an incident needing a product recall. The container code contains

information about the product that makes it easily identifiable to the manufacturer. Each code serves to link the container with a specific time frame in which the product was processed and packaged. If you package your product in a hermetically sealed container, you MUST include container coding on each of your containers. Processors of acidified foods must follow regulations for container coding as listed in 21 CFR 114.

For each container that needs coding, the code must be marked on the containers so that it is permanently visible to the naked eye. Codes can be imprinted or embossed directly on the container. If that is not a possibility, codes may be legibly perforated or otherwise marked on the label, so long as the label is securely affixed to the product container.

The code should be developed so the following can be identified:

- the establishment where the product was packaged;
- the product contained within the package; and
- the year, day, and period during which the product was packed.

The code for the packing period should be changed with enough frequency to enable easy identification of lots during sale or distribution. Codes may be changed periodically on one of the following bases: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers constituting the batch do not represent those processed during more than one personnel shift.

For USDA regulated products, codes must be able to identify:

- the product (unless the product name is lithographed or printed directly on the container); and
- the day and year packed.

There are a variety of ways to code your product in order to identify the information required. One popular method is called the Julian Date coding system. For example, the Julian Date coding system was used to generate the product code 198G1115, where:

- "198" stands for the day of the year (1-365);
- "G" stands for the month of the year (A-L);
- "11" stands for the year packed (2011);
- "1" stands for the production facility (if more than one facility); and
- "5" stands for the hour it was made or the batch number.

STEP 9: REGISTER YOUR FACILITY WITH THE FDA

The FDA requires all food facilities that are processing food products in the United States to register with the FDA. This is done with a simple form that asks for the physical location of the processing facility and the main contact for that facility.

For more information, visit www.access.fda.gov.

STEP 10: FILE YOUR SCHEDULE PROCESS WITH THE FDA

In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers (21 CFR §§ 108.25(c)(2), 108.35(c)(2)).

Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (§113.87(a)). You must register your facility with the FDA before you start processing any acidified foods recipes. See 21 CFR 108.25(c)(1).

STEP 11: SUBMIT ACIDIFIED FOOD FILING TO THE FDA AFTER FINAL PROCESS APPROVAL IS RECEIVED FROM THE GDA

When you receive the process authority letter of approval and the scheduled process for your recipe, complete FDA form 2541a using the critical factors and other process information described in the letter provided by the process authority. See 21 CFR 108.25(c)(2). No fee is required for filing.

To file online: If you have already created an online account with the FDA, you must log on to your account and follow directions to file your process online. The following link provides instructions for filing FDA Forms 2541 and 2541(e): www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm

A hardcopy of the FDA form 2541e can be obtained at: www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465593.pdf or by contacting the LACF Registration Coordinator at 301-436-241.

To file by mail (paper filing only): Mail completed FDA form 2541A to the FDA at the following address: LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition Food and Drug Administration, 5100 Paint Branch Parkway College Park, MD 20740.

STEP 12: REQUEST A GDA FINAL ON-SITE PROCESS REVIEW AND LICENSING INSPECTION

It is very important to maintain a good working relationship with the staff and inspectors at the GDA Food Safety Division and Manufactured Foods Section because you will be depending on them for as long as you are processing your food product. Their website is www.agr.georgia.gov/foodsafety.aspx—get to know what they do and how they can help you!

When the final process approval has been issued for your product, an on-site review and licensing inspection should be done on your facility by GDA inspectors. Call the GDA Food Safety Division to arrange an approval inspection. At this time, you will demonstrate completion of all the aforementioned requirements. The GDA will request copies of your scheduled process approval and FDA form 2541a for each product, product label, batch sheet used to record critical factors set forth by the process authority, and any other information that they need to complete their review. You will also be required to demonstrate your knowledge and ability to meet the sanitation and process requirements for the production of acidified foods. This includes proficient use of your pH meter (21 CFR 114.90).

Have you completed these steps?

- ☐ Registered your processing facility with FDA in regards to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002: www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm (Form 2541)?

- ☐ Submitted FDA form 2541e to the FDA for each acidified foods recipe and received approval on the filing?
- ☐ Completed the daily processing log each time you process a product for sale?
- ☐ Kept your records up to date and available for inspection?
- ☐ Made copies of all required forms and reports for review by the inspector?

The staff of the Georgia Department of Agriculture's Food Safety Division is available to advise and guide you through all the steps listed above. For more information contact them at www.agr.georgia.gov/foodsafety.aspx.

STEP 13: DEVELOP A RECALL PLAN

A commercial processor engaged in the processing of acidified foods is required by 21 CFR 108.25 to prepare and maintain a written recall plan. Guidelines for product recalls are contained in 21 CFR 7. Recall is a voluntary action taken by manufacturers and distributors to remove food that is in violation of laws administered by the FDA.

This plan will provide a current procedure for implementation, including:

- notification to the FDA of any recalls;
- a documented procedure for distributors to follow to recall products that may be injurious to health;
- a documented procedure for identifying, collecting, warehousing, and controlling products; and
- a method for determining the effectiveness of any recalls.

Recall is a time consuming process and could be a costly affair for small and very small processors. It may often destroy a company's reputation and future business prospects. Careful control over production and processing is an absolute necessity to prevent the need for a recall. In the event a recall is necessary, use the plan, paying close attention to the notification step, the use of designated spokespersons, and good communications to all involved.

Careful planning will allow the processor to implement the recall in a timely, organized fashion with a minimum of confusion. This will help to minimize the public health consequences and losses to the company.

DEFINITIONS

Acid Foods
Foods, including fermented foods that have a natural pH of 4.6 or below. Natural pH means the pH prior to processing. However, if during processing the pH rises above 4.6 (through washing, lye peeling, etc.) and an acid or acid food is added to reduce the pH to 4.6 or below, that product would be considered an acidified food.

Acidified Foods
Low-acid foods to which acid(s) or acid food(s) are added and which have a water activity (A_w) greater than 0.85 and a finished equilibrium pH of 4.6 or below.

Commercially Sterile Product
Food in a hermetically sealed package that will not allow any viable microorganisms to grow and in which microorganisms cannot be detected by usual bacterial culturing methods.

Clostridium botulinum
A spore-forming bacteria that is capable of forming a toxin under anaerobic conditions. The toxin is extremely deadly even in small doses. The toxin is destroyed by heat; therefore, it is recommended to bring home-canned foods to a rolling boil before consumption.

Equilibrium pH
The condition achieved when the solid and liquid parts of the product have the same pH. When an acid such as lemon juice is added to whole peppers, equilibrium might not be reached for several hours or several days. The product may need to be refrigerated until a pH of 4.6 is reached. The pH can be determined immediately after processing by blending the entire contents of the finished product container and taking the pH or by blending the solid particles and acid brine in the proportion present in the finished product and taking the pH.

Exempt Foods
These foods may be called pickles or pickled food. In addition, the following are excluded from regulation 21 CFR 114: carbonated beverages, jams, jellies, preserves, acid foods 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 (this includes such foods as standardized and non-standardized food dressings and condiment sauces), and foods that are stored, distributed, and retailed under refrigeration. Jams, jellies, and preserves covered by the standard of identity (21 CFR 150) are exempt foods if the water activity is 0.85 or less and the pH is 4.6 or less.

Fermented Foods
Low-acid foods subjected to the action of certain microorganisms that produce acid during their growth and reduce the pH of the food to 4.6 or below. They may be partially desalted, processed, or preserved in the original salt brine, in new salt brine, or in a vinegar solution with other ingredients. Foods partially fermented require addition of acid to reduce the pH to 4.6 or less.

Hermetic Seal
A package that is under anaerobic conditions, that is, lacking the oxygen necessary for the growth of organisms that contaminate food.

Lot
The product produced during a period indicated by a specific code.

Low-acid Foods
Any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (A_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classified as low-acid foods.

Scheduled Process
A process used to manufacture a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority. The process that is filed on Form FDA 2541a is considered to be the scheduled process. The critical factors necessary to achieve and maintain a safe product are listed on the process filing form. They shall be controlled, and records of the results of tests or determinations kept.

Water Activity (A_w)
A measure of the free moisture in a product, which is a measure of relative humidity within the product. Any food that always has 0.85 water activity or less is excluded from coverage under 21 CFR 113-114.

APPENDIX

Extension Food Science Outreach Program
240 Food Science Bldg., 100 Cedar Street
The University of Georgia
Athens, GA 30602-2610

EFS Office phone (706) 542-2574
PA/NFP staff phone (706) 542-9069
Process Approval email prosaprv@uga.edu
NFP email nfp@uga.edu

PROCESS APPROVAL
FOR ACIDIFIED FOOD PRODUCTS
(for Georgia Residents only)

PLEASE NOTE: This form is intended **only for an acidified food product** that is to be packaged in a sealed and labeled can /jar/bottle. Once your process for this product is approved, a letter of process approval will be issued to the Georgia Department of Agriculture's Manufactured Foods Division, who will then contact you.

Please allow at least two weeks per product from the date we receive all of your information and payment. This form can be saved to your computer, then print and fax to (706) 583-0992, or mail a copy of this form with your payment to the address above. Payment in advance is required. Use the separate EFS Services Payment Form to calculate your fees, then print and fax it to (706) 583-0992 or mail with your product information.

Product Name:

Owner

Contact (if different from owner)

Company

Address

City/State/Zip

County of Residence

Phone

Fax

Email

Where will your product be manufactured?
My kitchen (licensed & inspected by GDA)

Co-Packer

Phone

Email

Send a copy of this form with one sample of this product, packaged as it will be when it goes on the market, to:
Process Approval
UGA Extension Food Science
240 Food Science Bldg.
100 Cedar St.
Athens GA 30602-2610

If you plan to process an acid or acidified product yourself in a licensed and inspected commercial kitchen, you must have completed and passed ***Better Process Control School*** training prior to requesting a Process Approval for any product. If you use a co-packer, have them fax or email their BPCS certificate.

passed the Better Process Control School at (location)

on

Fax BPCS certificate to (706) 542-9066 or scan and email to prosaprv@uga.edu.

Process for _____ **Company** _____

PROCESSING INSTRUCTIONS for

_____

Recipe/Formulation of Your Product – List all ingredients in your recipe for one batch of product, using accurate measurements (i.e., grams, pounds, ounces, etc., not "pinch"!). Household measure is acceptable. ***If a commercially prepared product (such as mustard or mayonnaise) is used in your recipe, please send the ingredient label with your sample.*** If using an ingredient from a specific company, include company name and full ingredient name in the blank. Indicate if only this brand will be used for your product. If a food additive (i.e., gum, preservative, etc.) is used, type the name of ingredient as given by your suppler.

Amount	*Unit of Measure*	*Ingredient*

Process for _____ **Company** _____

pH Testing Procedures

Instructions for preparing samples and taking pH measurements are given on the last page of this form.

Raw pH of Mixed Ingredients before adding acidifying agent: _____
(to nearest hundredth - e.g., 4.80)

pH of Acidifying agent(s) used in this product (to nearest hundredth - e.g., 3.25)*
* ***Pour a small amount of the acidifying agent (about ¼ cup) into a clean jar or cup and take pH with calibrated pH meter and probe, to the nearest hundredth (two numbers after decimal). Do not measure in the bottle. Enter pH in the box beside the acidifier(s) used in your recipe. Leave the other boxes blank.***

_____ **Vinegar / Acetic Acid** _____ **White Vinegar** _____ **Apple Cider Vinegar**

_____ **Citric Acid** _____ **Tomato** _____ **Lime Juice** _____ **Lemon Juice**

Other Acidifer (please type name and its pH below):

_____

Method of acidification: ☐ **Batch** ☐ **Direct** ☐ **Indirect**

Preservatives used (if any):

_____

Maximum equilibrium pH of product (to nearest hundredth - e.g., 3.97)*: _____

***** ***Open one container of product 24 hours after processing and packaging/sealing. Using a clean probe and calibrated pH meter to take pH reading. DO NOT REFRIGERATE sample before taking pH!***

Product Classification *(to be completed by process authority)*

Based on the recipe, product formulation, and the maximum equilibrium pH, this product has been classified under 21 CFR 114 as:

☐ **Acid** ☐ **Acidified** ☐ **Low-Acid** ☐ **Exempt**

Reviewer's Comments

_____

Process for _____ **Company** _____

Containers & Closures *

Check here if using more than one container size/shape.

Container 1 Type: ☐ Glass Bottle ☐ Glass Jar ☐ Plastic (PET) Bottle ☐ Metal/steel can ☐ Aluminum can ☐ Flexible Pouch

Container not listed above - please give details below:

_____

Container 1 Shape: ☐ Round ☐ Square ☐ Rectangular ☐ Irregular

Container 1 Dimensions (in inches only): *

_____ **Length** _____ **Width** _____ **Height** _____ **Thickness** _____ **Volume (fl. oz., to the nearest whole number)**

The FDA container dimension codes for Container 1 are:
See details of how the container dimension code is calculated in the box below

_____ **Length** _____ **Width** _____ **Height** _____ **Thickness**

Container 2 Type: ☐ Glass Bottle ☐ Glass Jar ☐ Plastic (PET) Bottle ☐ Metal/steel can ☐ Aluminum can ☐ Flexible Pouch

Container not listed above - please give details below:

_____

Container 2 Shape: ☐ Round ☐ Square ☐ Rectangular ☐ Irregular

Container 2 Dimensions (in inches only): *

_____ **Length** _____ **Width** _____ **Height** _____ **Thickness** _____ **Volume (fl. oz., to the nearest whole number)**

The FDA container dimension codes for Container 2 are:
See details of how the container dimension code is calculated in the box below

_____ **Length** _____ **Width** _____ **Height** _____ **Thickness**

*** FDA uses a two-part code for the dimensions of the container measured in inches. This information is critical for completing your scheduled process filing on FDA form 2541a.**

The first part of the code is the whole number of inches in the dimension. The second part represents the fraction of inches in sixteenths.

For example:

1. If the dimension is a whole number in inches, create the code with that number and two zeros. 4 inches = 400
2. If the dimension is 5 15/16 inches, create the code from 5 and 15 = 515
3. If the dimension is 3 3/4 inches, convert the 3/4 inch to sixteenths (12/16), then create the code = 312
4. If the dimension is 4 and 1/8 inches, convert the 1/8 inches to sixteenths (2/16), then create the code from 4 and 2 = 402

Process for _____ **Company** _____

Closures/Caps to Be Used for this Product

☐ **One-piece screw-on lid with seal**

☐ **Two-piece lid with seal and screw-on ring**

☐ **Heat sealed foil with plastic cap**

☐ **Tamper-evident safety seal**

Other Closure(s) used - *provide details below*

Product Cooking/Heating (if applicable):

Equipment used for product cooking/heating:

☐ **Steam Jacketed Kettle** ☐ **Pressure Cooker** ☐ **Kettle/Pot**

Manufacturer Name: _____

Model: _____

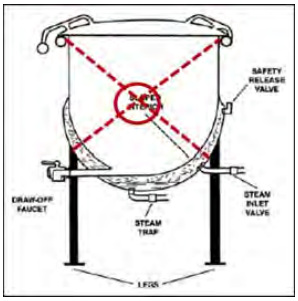
Heating Medium: _____

Temperature of Mixture Before Start of Cooking: _____ **°F**

Maximum Cooking Temperature: _____ **°F**

Measure at the geometric center of cooking vessel

Please give details of any special features on your thermal processing equipment (such as a mixer - self-propelled, hand-held, or motorized external add-on, etc.):



Process for _____ **Company** _____

Method of Thermal Processing/Sterilizing Filled Containers

☐ **Hot Fill / Hold** ☐ **Water Bath (not pressurized)** ☐ **Pressure Canner (pressurized)** ☐ **Retort**

Packing Medium*: _____

***** *The packing medium is usually the liquid portion(s) of the product that is added over, or added to, the solid portion(s) of the product. Examples of packing medium include: water, brine, sauces, and other liquid coverings. If there is no liquid packing medium, enter "solid pack" as the packing medium.*

Fill Temperature*: _____ **°F**

* *Measure temperature (at geometric center of container) in the* ***first filled container****, before capping. Rinse and dry the thermometer after recording the temperature.* ***Minimum recommended temperature is 180° F . If the product is not higher than 180° F, it should be re-heated before filling containers for product safety.***

Finding the geometric center

Hold Temperature*: _____ **°F**

* *Measure temperature (at geometric center of container) for the* ***last filled container*** *in the same batch. The container must be sealed and a hole punched in the center of the lid to insert the calibrated thermometer or probe.* ***Minimum recommended temperature is 180 °F.***

Time when thermometer is inserted into sealed container: _____

Time when internal temperature comes down to 180°F: _____

Hold Time* = _____ **minutes**

* *Calculate HOLD TIME using the time when the thermometer was inserted through the lid into the last filled container as the start time, and the time when the temperature of the contents comes down to 180 ° F as the end time. If the temperature in the last container filled is NOT above 180 ° F at the start time, the product should be re-heated for product safety.*

I hereby acknowledge that all of the information provided in this form is accurate to the best of my knowledge. I also acknowledge that if any information is missing or is not accurate as reported on this form, or if there is any change from the stated information on this form (e.g., change in product recipe, processing procedure, container size, etc.), I will notify UGA Food Science Extension as soon as I learn of these changes and request a revision of the process approval.

_____ **(signed)** **Date** _____

Owner/Processor Signature

Process for _____ **Company** _____

SCHEDULED PROCESS APPROVAL – FOR PROCESS AUTHORITY USE ONLY

To be calculated by the process authority

Least Sterilizing Value: Not applicable ☐ **F_o** ☐ **IS Value** ☐

Least Sterilizing Value for this Process:

Start Temp (center) _____ **°F** **Processing Time** _____ **min.**

Death Rate (z value) _____ **°F** **Ref. Temp.** _____ **°F**

Least Sterilizing Value (F_o) _____ **min.** **pH of furnished sample** _____

(Attach EFS pH report to this record)

Comments from process authority:

DISCLAIMER: UGA Food Science Extension will not be held liable and/or responsible for any missing or incorrectly reported information on the attached form.

This process (as given in the attached form) meets the requirements for processing an acidified product. This approval is given based solely upon the information provided. If any changes are made to the recipe or processing of this product by the manufacturer, this approval becomes null and void.

This process has been approved by **Date** _____

[redacted] **Ph.D.** _____ [redacted] **Ph.D.** _____

Process for _____ **Company** _____

Appendix A: Instructions for performing pH testing

Equipment Needed: pH meter, electrode, piercing electrode (for whole ingredients like okra or cucumber), buffer solutions 7.0 and 4.0, distilled water, lint-free drying cloths, #8 sieve

Instructions for measuring pH for liquid mixture (no solids):
1. Shake or stir product until all ingredients except the acidifier are mixed well.
2. Pour about ¼ cup into a clean jar or cup.
3. Measure pH with a calibrated pH meter and electrode. Take three separate readings. Be sure to clean the electrode by rinsing well and blotting dry on a clean paper towel between each reading.
4. Record the raw pH readings below and on page 3 of the Process Approval form.
5. Rinse electrode with distilled water and blot dry on a clean paper towel before testing the sample again.
6. Take this measurement at three places in your sample and record them on this form.

Instructions for measuring pH for chopped or semi-liquid products:
1. Before you add the acidifier ingredient (vinegar, lemon or lime juice, etc.) to your recipe, measure put all of your other ingredients in the recipe into your mixing bowl or kettle and stir together until well distributed.
2. Dip out about ½ cup of your mixture with as many of the low-acid ingredients in the sample as possible.
3. Drain off any liquid with a #8 sieve into a container.
4. Weigh and record the weight of the liquid and solid ingredients.
5. Put the drained sample into a clean blender bowl and blend until smooth.
6. Using a calibrated pH meter and clean electrode, stir the electrode around in the blended ingredients. Do not allow the electrode to touch the bottom or sides of the bowl or cup.
7. Record the results below and on page 3 of the Process Approval form.
8. Rinse the electrode with distilled water and blot dry on a clean paper towel before testing the sample again.
9. Take this measurement at three different places in your product and record them on this form.

Instructions for measuring pH for whole ingredients (cucumbers, okra, etc.):
1. Wash and prepare whole ingredients to be used in this recipe.
2. Before placing them into a canning jar, insert a piercing pH electrode into center of the whole ingredient.
3. Record the results for this batch below and on page 3 of the Process Approval form.
4. Rinse the electrode with distilled water and blot dry on a clean paper towel before testing the sample again.
5. Take this measurement at three different places in your sample ingredients and record them on this form.

IMPORTANT: Prepare the raw ingredients before adding the acidifier as instructed above. Take three pH readings with a calibrated pH meter, rinsing the probe and blotting it dry with a clean paper towel between each reading. Record in the RAW pH column below.

Take three pH measurements at different levels of your sample 24 hours after processing. Calibrate your pH meter each day before taking pH measurements (see instructions). Rinse pH electrode with distilled water and dry with clean paper towel after taking each pH reading. Enter actual readings below (DO NOT AVERAGE):

Product Name		***Lot Code:***
Raw pH (measure before acidification)	***Equilibrium pH (24 hrs. after processing)***	***Internal pH of Solid Ingredients (such as cucumber spears, okra, etc) (24 hrs. after processing, use piercing electrode)***
1.		
2.		
3.		

NOTES

extension.uga.edu/publications

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