pennsylvania
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES

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CANNING OF ACID, ACIDIFIED, FERMENTED FOODS & BEVERAGES GUIDANCE FOR PA LIMITED FOOD ESTABLISHMENTS

This guidance document is intended only for firms that currently hold or intend on obtaining a Limited Food Establishment registration in Pennsylvania. Firms that will be operating out of a commercial style kitchen should reference the guidance documents for Food Establishments.

DEFINITIONS:

Limited Food Establishments (LFE's) are classified in PA as homestyle kitchens that are registered and inspected by PDA. These firms are approved to produce foods that are non-TCS (do not require time or temperature control for safety) only. Additional information on obtaining a registration can be found on PDA's Limited Food Establishment webpage.

Acid foods are foods that have a natural pH of 4.6 or below. Examples include: most fruits like apples, peaches, lemons, etc.

Formulated Acid Foods are foods composed mostly of acid foods to which a small amount of low-acid ingredients are added (generally less than 10% by weight). The low proportion of low-acid ingredients means the pH doesn't change significantly from the pH of the dominant ingredients. Examples may include: some BBQ sauces, some dressings, mayonnaise.

Low-acid foods have an equilibrium pH above 4.6 and water activity above 0.85. Examples include: most soups, gravies, un-pickled vegetables, and fruits with pH ranges above 4.6.

Acidified foods are defined by the FDA as low-acid foods to which acid(s) (vinegar or lemon juice) or acid food(s) are added and which have a finished equilibrium pH of 4.6 or below and a water activity (a_w) greater than 0.85. Examples may include: some salsas, chow-chow, pickled vegetables, hot sauces.

Fermented Foods – foods subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below. Examples include: kombucha, Korean kimchi, sauerkraut, some pickles, and green olives.

Scheduled Process – the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining 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.

Processing Authority – an individual or organization with sufficient academic degrees, experience, and ability to evaluate the microbiological safety of products. A current list of processing authorities can be found on the AFDO website or by contacting Penn State Department of Food Science.

Water Activity (a_w) – a measure of the free moisture in a product. This is **not** the same as "percent water" in a product.

pH – a figure expressing the acidity or alkalinity of a solution in which 7 is neutral, lower values are acidic, and higher values are alkaline.

REGISTRATION:

Requirement to Register with PDA- Firms that intend to manufacture foods are required to register with PDA. Additional information and registration information can be found at **PDA Manufactured Food Registration**.

Requirement to Register with FDA- Firms that are conducting interstate commerce **and** are conducting >49% wholesale sales should register their food facility with the FDA: Registration of Food Facilities| FDA If the firm is subject to modified requirements of 117 than the firm shall also register for qualified facility attestation: Qualified Facility Attestation | FDA

Requirement to Register scheduled process with the FDA- Acidified Food Processors must register their process with the FDA if they will be conducting interstate commerce. For additional information on what is considered to be interstate commerce of ingredients, packaging and final product please refer to the FDA reader. Registration of processes can be completed through the FDA's website.

BEVERAGES / DRINKS / JUICES

Some beverages may be permitted to be produced at limited food establishments. These may include Root Beer, Lemonade, Lemon Iced Tea, Kombucha*, and other acidic or fermented drinks. pH must be tested on all drinks/beverages to assure the pH is less than 4.6. However, producers of bottled or canned fermented beverages should aim for a pH level of 4.2 or below.

Acidified drinks or drinks to which an acidifying agent is added to bring the pH to below 4.6 must have a scheduled process completed by a processing authority if the product final pH is above 4.2. Examples may include Lemon Iced Tea.

Fermented drinks that are 'bottled' or 'canned' are required to have a processing step that impedes or stops the fermentation process. Employing refrigeration alone to control the continuing fermentation will not be approved for limited food establishments. Pasteurization at 180°F is one confirmed option for fermented drinks produced by limited processors. Commonly made fermented drinks include kombucha and kefir.

** See "Guidelines for brewing/bottling Kombucha" for more information.*

Freshly Brewed Coffee & Tea are considered TCS (requiring time and temperature control for safety) foods due to their high pH (>4.6) and are not permitted to be made under an LFE license unless shown to have a pH < 4.6.

100% Juice products may be permitted to be made at a LFE under certain circumstances. The FDA defines juice as the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. (100% percent juice under 21 CFR 101.30, or a concentrate of that juice for subsequent beverage use).

Juices processed in a limited food establishment must be tested for pH to determine whether they are non-TCS foods (do not require time or temperature control for safety). Only juices with a pH of 4.6 or below may be produced in this type of establishment.

Juices produced in a limited food establishment may ***only be sold directly to the consumer*** from the either the production site or from a satellite of the production site, such as a farmer's market or roadside stand owned by the producer. Products **may not cross state lines (including internet sales)** if a Juice HACCP plan has not been pre-approved through PDA.

Juices produced in a limited food establishment are subject to the labeling regulation in 21 CFR 101.17(g), which requires a warning statement on fruit and vegetable juice products that have not been processed in the manner to prevent, reduce, or eliminate pathogenic microorganisms. These untreated products should be kept under refrigeration, as an additional step in reducing pathogen growth, and are required to carry the following warning statement on the label:

> ***WARNING:*** *This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.*

NOTE: *Product testing as described below under "Canning of Acid/Acidified/Fermented Foods" would be applicable to canned or vacuum sealed beverages/drinks and juices.*

CANNING OF ACID/ACIDIFIED/FERMENTED FOODS

LFE's may only "can" food products that reach a pH of 4.6 or less upon completion of the recipe (a combination of pH (acid level) and water activity (a_w) may also be evaluated). Examples of these types of food products that might be approved for canning include:

- ✓ Naturally acidic foods (e.g. most fruits like apples, peaches, lemons, etc.)
- ✓ Fermented foods (e.g. Korean kimchi, sauerkraut, some pickles, green olives, etc.)
- ✓ Acidified foods (e.g. some salsas, pickled vegetables, hot sauces, and BBQ sauces.

Producers of acidified foods *must have written recipes / formulas and procedures*. You will need to provide a Process Flow for your products and have it approved by your Food Inspector prior to registration and sale of your product. If you are unsure if your product is considered an Acid, Acidified or Fermented Food, please discuss with your Food Inspector.

❖ INITIAL PRODUCT TESTING

Initially, the producer shall have each unique recipe/product tested by an independent ***commercial food laboratory*** and test results submitted with the application for review. Producers of acidified/ fermented foods or beverages will be approved only if testing results for equilibrium pH show that their products fall within safe ranges of ***pH 4.6 or below*****.** However, producers of acidified/fermented foods or beverages should aim for a pH level of 4.2 or below as an extra precaution.

If your product qualifies as an acidified food and the equilibrium pH is **>4.2 you must have a scheduled process developed** by a competent processing authority. A current list of processing authorities can be found at AFDO.

❖ ONGOING PRODUCT TESTING & RECORD KEEPING

- *If your final equilibrium pH is 4.0 or below*, you must have either a properly calibrated pH meter or ***pH test strips*** to verify your pH of every batch produced. If the product color inhibits accurate reading by pH strips you are required to use a pH meter for batch testing.
- *If your final equilibrium pH is between 4.0 and 4.2*, you must have a properly calibrated ***pH meter*** and check the pH of every batch produced.

  If your final equilibrium pH is between 4.2 and 4.6, you must have a properly calibrated pH meter and check the pH of every batch produced. Additionally, you must have your product flow, recipe and process evaluated and approved by a ***Process Authority.*** Ball canning recipes developed after 1994 and USDA canning recipes are not required to be re-evaluated by a processing authority **ONLY if no changes to the process or formulation are made, including container size and type**. (A process authority is a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.)
- *If your final equilibrium pH is above 4.6 (and a_w above 0.85)*, see the "low acid canned foods or beverages" section below.

All records pertaining to monitoring pH as the critical process control (pH log sheets) must be kept showing production date, batch number, pH, pH meter calibration records, container check records, supplier and purchaser information and any corrective actions taken to correct deficiencies noted if pH was 4.6 or above. Records showing verifications and calibration of the pH meter must also be kept**. No product may ever enter commerce if a final pH is found to be >4.6 during testing.**

How to properly test for equilibrium pH of batches prepared after approval

Equilibrium pH is the final pH in the food product after the acidic brine or ingredient is allowed to sit and balances its pH with all ingredients.

For a proper pH reading, you should test the pH of the product roughly 24 hours after processing, once the containers have cooled to room temperature and stabilized, or as directed by the processing authority that evaluated the process. **Do not take the pH of a product just before or right after canning because it will not be an accurate measure of the equilibrium pH**.

- *If a food is homogeneous*, that is of uniform consistency (apple sauce, barbeque sauce, ketchup, etc.), then the pH of any portion may be representative of the whole and tested for pH.

- *If the food is semi-solid* (e.g. puddings, chunky salsas, and very thick sauces), these foods should be **blended to a uniform paste** before testing. If additional liquid is required to blend the samples, use distilled water (20 parts of distilled water/100 parts of food).
- *If the food consists of a mixture of liquid/solid foods* (e.g. pickled vegetables, etc.), then you need to **purée this in a blender**, with distilled water if necessary, into a slurry before testing. The solid portion may differ in acidity from the covering liquid (brine). Therefore, it is necessary to test both components in order to determine the equilibrium pH. This can be done either by blending fractions of both solid and liquid portions in the same ratio as found in the original container or simply by blending the entire contents of the container to a uniform paste and then test for pH.

pH meter purchase guidance

If you are producing a food product with a pH of 4.0 or higher, it is required that you use a pH meter with an accuracy rating of 0.01 + pH units. If producing an acidified food with a pH below 4.0, it would be best to purchase a pH meter that has an accuracy rating of 0.1 + pH units. All pH meters should have buffer solutions and should be calibrated with the buffer solutions before use each production day.

❖ THERMAL PROCESS & RECORD KEEPING

Generally, recipes of acidified foods must incorporate a thermal process (heat step) to ensure its safety and shelf stability by destroying the pathogenic and spoilage microorganisms that might be present in the product and on the container.

For acidified canned foods, safety can be achieved by employing one of the following methods:

a. ***Hot-fill-hold process –*** the product is cooked and filled at a temperature of 180°F (or above) and a closure or lid is applied. The sealed container is inverted and held for 1 minute or longer to ensure pasteurization of the container headspace and inside surfaces. The container is then turned right side up and allowed to air cool. Processors may choose to hold the inversion longer to ensure safety and that a strong seal is achieved on the container. Additional hot fill hold processes, as determined by a process authority may also be applied.

   This type of process is mostly used for foods with smooth consistency (e.g. sauces, salsa, etc.)

b. ***Water bath or steam (canning) process*** – the preheated product is filled into the container and the closure is applied. The container is subjected to boiling water bath or steam canning until the coldest spot in the container reaches 180°F or above for 25 seconds or longer.

   Additional water bath processes, as determined by a process authority, may also be applied.

c. ***If the recipe does not allow for a heat treatment*** (e.g. oil-based formulation, emulsions, etc.), an alternative process where safety can be assured without a heat process may be employed if the following conditions are met:

- ✓ Final pH is adjusted to 3.3 or below.
- ✓ Acetic acid (i.e. vinegar) is used as the primary acidulant and/or benzoic acid is added as a preservative.
- ✓ Product must be held at 77°F or higher for a minimum of 48 hours prior to distribution.

It is the combination of the specific killing effect of acetic acid, benzoic acid, low pH and hold temperature and time that ensures safety.
Additional processes, as determined by a process authority, may also be applied.

All records pertaining to monitoring of the thermal process (e.g. time, temperature) must be kept for each batch produced as well as records of verifications (thermometer & pH meter calibration, etc.), container checks, and corrective actions taken to correct deficiencies noted on the process records.

Additional Requirements:

- ✓ Anytime a recipe is altered, or a new recipe is developed, the final product must be tested as described above.
- ✓ Use only clean and sanitary equipment/ utensils and adhere to good manufacturing and personal hygiene practices (to prevent cross-contamination and allergen cross-contact).
- ✓ Use only new lids. Re-used jars may be allowed but they must be thoroughly washed, sanitized and visually inspected for cracks, chips or defects that would prevent a proper seal during the canning process.
- ✓ All labeling requirements on the containers must be met, including a code or lot number for traceability.
- ✓ *Processors wishing to sell their products interstate (which include internet sales) may be required to register with the US Food & Drug Administration (FDA). If you are unsure of federal regulations that apply to your situation, contact your local FDA Small Business Representative.*
- ✓ *FDA will require acidified food recipes to be reviewed by a Process Authority, to file processes with FDA, and to batch test all products under their jurisdiction, regardless of pH level. These requirements should be discussed with FDA if you intend to sell products in interstate commerce. For more information contact the FDA at 1-888-463-6332.*

LOW ACID CANNED FOODS OR BEVERAGES

Generally, any food/beverage with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85, is considered a low-acid food. Low acid canned foods or beverages may only be processed in a commercial establishment using a steam retort system. They may **NOT** be made from a limited food establishment or in any residential-style kitchen. This would include, for example, most soups, gravies, un-pickled vegetables, and fruits with pH values greater than 4.6.

For more guidance on acidified and low-acid canned foods visit the FDA's Acidified & Low-Acid Canned Foods (LACF) website.

OTHER FOODS

Other types of foods may potentially be approved for processing, handling, re-packing or storage in a limited food establishment; however, only those foods considered non-TCS foods are permitted to be produced/held in this type of setting. Product testing for pH and water activity (a_w) may be required on a case by case basis for questionable foods to determine whether they are a TCS food. If you have an unusual food product, discuss this product with your Food Inspector.

ADDITIONAL RESOURCES:

Penn State Cooperative Extension Website assistance for navigating starting a small food operation, trainings for food processors and resources for acidified food producers.
2015 USDA Canning Guide link to NCFP website where a pdf copy is available for download.
Penn State Department of Food Science for technical assistance and training opportunities (814) 865-5444
File a scheduled process with the FDA link to forms and instructions for registering with FDA
Acidified Food Regulations 21 CFR 114
AFDO List of Processing Authorities