

CANNING OF ACID, ACIDIFIED & FERMENTED FOODS GUIDANCE FOR COMMERCIAL FOOD ESTABLISHMENTS LICENSED BY PDA

This document is intended as a guidance document for firms that hold, or intend to receive, Food Establishment registration through the PA Department of Agriculture with the intention of producing canned food products that are classified as Acid, Acidified or Fermented. Additional guidance is available for firms that intend to apply or currently hold LFE (Limited Food Establishments) licenses through PDA.

DEFINITIONS:

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 in syrups.

Acidified foods are defined by the FDA as low-acid foods to which acid(s) (typically 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 (aw) greater than 0.85. Examples may include: some salsas, some sauces, and pickled vegetables.

Equilibrium pH - The condition achieved when the solid and liquid parts of the product have the same pH.

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, as 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 <u>AFDO</u> website or by contacting Penn State Department of Food Science.

Water Activity (aw) - a measure of the free moisture in a product. This is not the same as the 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:

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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 <u>PDA Manufactured Food</u> <u>Registration</u>.

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: <u>Registration of Food Facilities</u> FDA If the firm is subject to modified requirements of 117 than the firm shall also register for qualified facility attestation: <u>Qualified Facility Attestation | FDA</u>

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 <u>FDA reader</u>. Registration of processes can be completed through the <u>FDA's website</u>.

CANNING OF ACIDIFIED FOODS AND DRINKS

Some examples include: some salsas, some sauces, pickled vegetables, lemon iced tea

Producers of Acidified foods and drinks must test their products for pH at equilibrium and they <u>must</u> <u>have written recipes / formulas and procedures approved for all foods</u>. You will need to provide a Process Flow description for each of your products and have it approved by your Food Inspector **prior** to registration and sale of your product. Processors of acidified foods should work with a qualified person with expertise in acidified food processing (process authority) to develop their scheduled process and determine any critical factor(s) for their product (pH, time/temperature for heat treatment, etc.). A current list of processing authorities can be found at <u>AFDO</u>. Technical assistance is available through the Penn State Department of Food Science at <u>foodsci@psu.edu</u> or (814) 865-5444.

Initial Product testing and other requirements for acidified foods:

- Equilibrium pH results obtained from an independent laboratory.
- Processing Authority review/ development of scheduled process
- All recipes of acidified foods must incorporate a thermal process (cooking) to ensure its safety and shelf stability by destroying the pathogenic and spoilage microorganisms that might be present in the product. For acidified canned foods, safety and shelf stability are achieved by employing one of following methods:
 - *Hot-fill-hold process* the product is cooked and filled typically at a temperature of 180°F (or above) and a closure or lid is applied (by a steam capper or by hand). 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 achieve on the container.
 - Water bath or steam (canning) process the preheated product is filled into the container and the closure is applied. The container is subjected to hot water bath or steam canning until the coldest spot in the container reaches at least the minimum required conditions of times and temperatures for safety.
 - *If the Acidified food 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. In these situations, a scheduled process is required and should be followed.



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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 calibration, etc.) and corrective actions taken to correct deficiencies noted on the process records.

Requirements for submission during plan review with PDA:

- Food Establishment Application- list all items intended to be processed
- Scheduled Process(es)
- Process Flow description or diagram for each of your products
- Recipe(s)/formulation(s) and procedure(s) (to include critical factors such as pH testing, time/temperatures during processing
- pH testing of proposed products

Employee Training Requirements- Supervision of processing activities shall be overseen by a qualified individual with appropriate training, as outlined in 21 CFR 114.10. This can include Better Processing School for Acidified Foods. These courses are offered through Penn State Cooperative Extension. A current list of courses can be found at <u>PSU Better Process Control Courses</u>.

Ongoing product testing and record keeping- These records should be maintained on site at the processing location and made available to inspectors during upon request:

- Batch Records- This should include date of production and should correlate with container markings for traceability.
- pH testing of products at equilibrium for each batch and products produced
 - All records pertaining to monitoring pH as the critical process control (pH log sheets) must be kept showing production date, product code, batch number, pH and any corrective actions taken to correct deficiencies noted if pH was 4.6 or above.
- If the final equilibrium pH is 4.0 or below
 - You must have either a properly calibrated pH meter, preferably capable of reading to 2 decimal places, or *pH test strips* to verify your pH of every batch produced. pH test strips may not be used if the color of the product interferes with an accurate reading of the test strips.
- If the final equilibrium pH is above 4.0
 - You must have a properly calibrated *pH meter* capable of reading to 2 decimal places and you must check the pH of every batch produced.
 - Records showing verifications and calibration of the pH meter must also be kept.
- Time/ Temperature records for each batch
- Container check records
- Corrective action reports for events when deviations from approved process occur

CANNING OF LOW ACID CANNED FOODS (LACF)

Some examples include: canned gravy, canned meats, canned vegetables

Low acid canned foods are foods that have a finished equilibrium pH above 4.6, a water activity above 0.85, and are stored without refrigeration.

Shelf- stable low-acid foods packaged in a hermetically sealed container (canned) may only be processed in commercial establishments with adequate and approved LACF equipment (e.g. steam retort system).



They must be processed under the regulation set forth in 21 CFR 113 and 108.35 in addition to GMP regulations. All processes must be filed with FDA and operations must be under supervision of a qualified individual through education (e.g. Better Process Control School) and/or relevant experience. These requirements should be discussed with FDA. See more information about federal requirements and FDA contact below.

For more guidance on acidified and low-acid canned foods, visit the FDA website at: FDA Guidance on Acidified Foods

CANNING OF ACID and FORMULATED ACID FOODS

Some examples include: canned peaches, canned apples

Acid Foods are defined as foods that are naturally occurring with a pH of 4.6 or lower. When canning acid foods, and formulated acid foods, a manufacturer shall follow 21 CFR 117 requirements specific to the food product. If the formulation of the acid food could present a possible deviation from the product's initial pH value, lab testing shall be obtained to verify it qualifies as an acid or formulated acid food.

Initial Product testing requirements for acid/ formulated acid foods:

• pH testing of product at Equilibrium obtained from an independent laboratory

Requirements for submission during plan review with PDA:

- Food Establishment Application- list all items intended to be processed
- Process Flow description or diagram for each of your products
- Lab tests for equilibrium pH of each product (if necessary)
- Recipe(s)/formulation(s) and procedure(s) (to include time/temperatures during processing)

Record keeping requirements:

• Firms should reference 21 CFR 117 to determine what food safety systems and appropriate records should be maintained for identified process controls such as pH

Employee training requirements:

• Firms shall reference 21 CFR 117 for employee training requirements.

CANNING OF FERMENTED FOOD AND DRINKS

Some examples include: *kombucha, kefir, sauerkraut, root beer

Producers of fermented foods must test for pH 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. Other process controls (in lieu of pH) may be applied to ensure safety of the product.

Initial Product testing requirements for fermented foods:

Product equilibrium test results obtained from an independent laboratory. Additionally, specific gravity testing may be required if alcohol is produced in the product as a byproduct of fermentation. Alcohol levels > .05% ABV may require additional licensing by the PA Liquor Control Board.



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Requirements for submission during plan review with PDA:

- Food Establishment Application- list all items intended to be processed
- Process Flow description or diagram for each of your products and lab tests for pH of each product.
- Recipe(s)/formulation(s) and procedure(s) (to include time/temperatures during processing) and specific gravity if appropriate

Record keeping requirements:

• Firms should reference 21 CFR 117 to determine what food safety systems and appropriate records should be maintained for identified process controls such as pH

Employee training requirements:

• Firms shall reference 21 CFR 117 for employee training requirements.

Fermented drinks that are 'bottled' or 'canned' need some type of processing step or combination of steps that impedes or stops the fermentation process including but not limited to refrigeration, heat treatment, etc.

(*) See "Guidelines for brewing/bottling Kombucha" for more information. The document can be found under References and Resources section

References and Resources

Link to PDA Food Establishment Registration Application *Link to PDA Handout Regarding Production of Kombucha FDA Registration of Low Acid Canned Foods and Acidified Foods FDA Registration of Food Facilities FDA Link to Qualified Facility Attestation FDA Link to 21 CFR 114 (Acidified Foods Regulations) FDA link to 21 CFR 117 (cGMPS, Hazard Analysis and Risk-Based Preventative Controls for Human Food AFDO Registry of Processing Authorities **PDA Modernized Current Good Manufacturing Practices (GMPs) Food Establishment Checklist** Penn State Cooperative Extension Website for Food Entrepreneurs Penn State Department of Food Science for technical assistance and training opportunities or (814)865-5444