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Pennsylvania Department of Agriculture Bureau of Food Safety and Laboratory Services 717-787-4315

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CANNING OF ACID, ACIDIFIED, OR FERMENTED FOODS & BEVERAGES -- GUIDANCE FOR PA COMMERCIAL FOOD PROCESSORS --

★ CANNING OF (ACID/ACIDIFIED/FERMENTED) FOODS

Examples of Types of food products under this category include:

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

Acid foods are foods that have a natural pH of 4.6 or below.

Low-acid foods have an equilibrium pH above 4.6 and water activity above 0.85.

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 (aw) greater than 0.85.

Producers of Acidified foods must test their products for pH and Water Activity (a_w) and they <u>must have written</u> <u>recipes / formulas and procedures</u>. 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. Processors of Acidified foods should work with a process authority to develop their scheduled process and determine any critical factors for their product (pH, time/temperature for heat treatment, etc.). 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. Contact your local university extension for a list of process authorities.

Processors of acidified foods offered for interstate commerce are required to register with FDA, file scheduled processes (through their process authorities), and the operation 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.

1. Initial Product testing:

Initially, the producer shall have each unique recipe/product tested for pH and a_w by an independent **commercial food laboratory** and test results submitted with the application for review. Producers of acidified/ fermented foods or beverages must obtain testing results for equilibrium pH showing 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.

2. Ongoing product testing and Record keeping

- If the final equilibrium pH is 4.0 or below, you must have either a properly calibrated pH meter or <u>pH test</u>
 <u>strips</u> to verify your pH of every batch produced.
- If the final equilibrium pH is above 4.0, you must have a properly calibrated pH meter and check the pH of every batch produced.
- o If the final equilibrium pH is above 4.6, 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 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.

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How to properly test for equilibrium pH:

Equilibrium pH is the final pH in the food product after the acidic brine or ingredient acidifies and balances with the other 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. 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.

- o <u>If a food is homogeneous</u>, that is of uniform consistency (apple sauce, barbeque sauce, ketchup, etc.), then the pH of any portion may be considered to be representative of the whole.
- 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).
- o <u>If the food consists of a mixture of liquid/solid foods</u> (e.g. pickled vegetables, etc.), then you need to purée this in a blender, with distilled water if necessary, into a slurry. 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.

More information about the use the pH meter and the sample preparation can be found in 21 CFR 114.90.

pH meter purchase guidance:

For guidance on how to purchase a pH meter, please visit Cornell University's fact sheet on <u>purchasing a pH</u> <u>meter</u>. Our general pH meter recommendations are if you are producing a food product with a pH of 4.0 or higher, it is best to purchase 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.

3. Thermal Process and record keeping

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, the safety and shelf stability are achieved by employing one of 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 (by a steam capper or alternately). 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.
 - This type of process is mostly used effectively 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 hot water bath or steam canning until the <u>coldest spot</u> in the container reaches at least the minimum required conditions of times and temperatures for safety*.
 - *Scientific studies were conducted and provide recommendation on the minimum processing time/temperature combinations to achieve a 5-log reduction in bacterial pathogens for acidified products.

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For acidified foods with an equilibrium pH of 4.1 or below: (partial table, see full table here)

Temp.(°F)	Time (min.)						
159	1.4	162	0.9	166	0.6	171-173	0.3
160	1.2	163	0.8	167-168	0.5	174-177	0.2
161	1.1	164-165	0.7	169-170	0.4	178-181	0.1

Reference: Food Protection Trends: Vol.30 No.5 p268-272

For acidified foods with an equilibrium pH of 4.1–4.6 (partial table, see full table here)

Temp.(°F)	Time (min.)						
154	12.9	160	5.6	165	2.8	170	1.4
156	9.8	162	4.3	167	2.1	175	0.7
158	7.4	164	3.2	169	1.6	179-180	0.4

Reference: Food Protection Trends: Vol.34 No.3 p132-138.

It is important to note that the recommended time-temperature processing conditions above are the minimum required at the coldest spot in the container; it is the type of food, food properties and type/size of the container that will dictate the final processing conditions, thus a thermal process must be established and approved.

- c. 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 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.

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.

4. Other requirements for canning:

- Anytime a recipe is altered or a new recipe is developed, the final product must be tested and approved 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 and sanitized.
- All labeling requirements on the containers must be met.

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↓ 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. This would include, for example, most soups, gravies, un-pickled vegetables, and fruits in syrups.

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: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/default.htm

♣ ACIDIFIED/FERMENTED BEVERAGES and DRINKS

Acidified/ fermented beverages and drinks include but not limited to Root Beer, Lemonade, Lemon Ice Tea, Kombucha (*), Water Kefir, and other fermented juices.

Producers of beverages/ drinks 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.

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 <u>HERE</u> under Publications Tab.

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

FRUIT & VEGETABLE JUICES

Juice means 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).

1. Producers of Juice who sell Retail ONLY

A retail establishment is an operation that provides juice directly to consumers and does not sell or distribute juice to other businesses. The term "provides" includes storing, preparing, packaging, serving, and selling juice. If you qualify as a retail establishment, you are not required to process juice under <u>Juice HACCP</u> regulation (21 CFR Part 120). However, packaged juice produced at a retail establishment is subject to FDA's food 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 products shall bear the following warning statement:

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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.

Juice producers/ retailers must have their products tested for pH to determine whether their product is a TCS food.
 TCS juices must be stored, distributed, and sold under refrigerated and must be labeled as such.

Product may only be sold direct to the consumer from the production site or from a satellite of the production site, such as a farmer's market or roadside stand owned by the producer.

In most cases, if product is sold from the production site in packaged form, only a Food Registration is needed. However, any retail location would need evaluated to determine if a Retail Food License would additionally be needed.

2. Producers of Juice who Sell Wholesale

All juice (as defined in 21 CFR 120.1(a)) sold as juice (or for use as an ingredient in other beverages) is subject to the requirements of the juice HACCP regulation set forth in 21 CFR 120.

Any juice of this type must be pasteurized or otherwise treated to have an approved and verified 5–log reduction of pertinent microorganism and must be processed using a hazard analysis and critical control points plan (HACCP). For more guidance, visit FDA website at: https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm

OTHER FOODS

Other types of foods may be reviewed on a case-by-case basis. Detailed processes and required testing results for pH and water activity (a_w) must be submitted along with the registration application. If you have an unusual food product, discuss this product with your Food Inspector.

FEDERAL JURISDICTION

The FDA Food Safety Modernization Act (FSMA) enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States register their facilities with FDA.

All commercial establishments engaged in the manufacture of Acidified Foods and LACF offered for interstate commerce or using ingredients obtained from interstate are required by 21 CFR Parts 108, 113, and 114 to register their facility with FDA, and file scheduled processes for their products (by their Process Authorities). If you are unsure of federal regulations that apply to your situation, contact your local FDA Small Business Representative at 1-800-216-7331 or 301-575-0156 or visit their website at:

http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm

These requirements should be discussed with FDA, especially if you intend to sell products in interstate commerce. For more information about process filing with FDA, visit their website at:

https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm Or contact FDA at 1-800-216-7331 or 301-575-0156.

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FSMA Preventive Controls for Human Food (PCHF) Rule

FSMA, a federal law enacted in 2011, requires eligible food establishments to follow the Preventive Controls for Human Food (PCHF) rule's new food safety requirements found in 21 CFR Part 117. Food establishments subjected to the rule must follow the updated good manufacturing practices (modernized GMPs), and to establish and implement a comprehensive PCHF food safety plan.

The Pennsylvania Department of Agriculture (PDA) adopts the new federal regulations as dictated by the Food Safety Act (3 Pa. C.S.A. §5733(f)) and will enforce all applicable provisions. All PDA registered firms will be expected to comply with the PCHF rule unless specifically exempted based on size.

Producers of LACF are partially exempt from PCHF 21 CFR 117 Subparts C and G with respect to C. botulinum control provided the firm is compliant with 21 CFR 113 and 108.

Producers of Juice products under Juice HACCP regulations are exempt from PCHF 21 CFR 117 Subparts C and G.

To determine whether you are affected by the FSMA PCHF Rule, check the Flow Chart at the link below: FSMA Preventive Controls for Human Food Rule-PDA Fact Sheet.pdf

For more information about PCHF requirements, visit:

FDA website at www.fda.gov/fsma

PDA website at: http://www.agriculture.pa.gov/Protect/FoodSafety/Pages/FSMA-Preventative-Controls.aspx,

PSU website at: https://extension.psu.edu/fsma

Training Opportunities:

Courses and workshops from the Penn State Department of Food Science: http://foodscience.psu.edu/workshops