Pennsylvania
Department of Agriculture

APPLICATION PACKET
FOOD ESTABLISHMENT REGISTRATION

LIMITED FOOD ESTABLISHMENTS

Food produced or stored in home or home-style kitchens

****This registration is not permitted in Philadelphia County***

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Enclosed are the necessary forms and application for obtaining a Registration as a "Limited Food Establishment" from the Pennsylvania Department of Agriculture. Types of operations that would be considered "limited food establishments" may include, but are not limited to:

- Warehousing (storing) food on a residential property,
- Processing/handling food from a home -residential kitchen,
- Processing/handling food in a residential-style kitchen (not meeting regulatory standards), in alternate locations, such as a church, fire hall, or remodeled garage area or out-building.

According to the Food Safety Act (*3 Pa.C.S.A. §§5721 – 5737*) "…it shall be the duty of every person operating a food establishment within this Commonwealth to register…"

SECTION 1:

PRODUCTION OPENING

Anticipated date to begin production: _____
Date

BUSINESS INFORMATION

NAME OF BUSINESS: _____

ADDRESS OF BUSINESS (LOCATION OF THE FOOD ESTABLISHMENT):

_____
Facility street number and name | City | State | Zip code

_____ _____
County | Township/Borough

(_____)_____ (_____)_____
Facility phone number | Facility fax number

_____ (_____)_____
Facility email address | Facility cell number or alternate phone number

MAILING ADDRESS (If Different Than Above):

_____
Street number and name | City | State | Zip code

SECTION 2:

ZONING APPROVALS

You must contact your local municipality (township office, borough office, town hall) to verify zoning approval to have a food business at this property. If you will be operating in a County Health Department, all applicable licenses/registrations issued by the County must be obtained **BEFORE** obtaining PDA license/registrations. *Please note: Any business selling food in Philadelphia County as a Limited Food Establishment requires NSF / ANSI equipment in a commercially zoned property.*

Name of Municipality: _____

I contacted my municipality on _____ (date) and confirmed that I can use this property or my residential home kitchen as the location for my limited food processing business.

SECTION 3:

OTHER CODES

Signature is required to affirm compliance with the checked requirements below. Attach any required supporting documentation.

☐ A license to collect sales tax has been obtained or applied for. For information on applying for a sales tax license, contact the Pennsylvania Department of Revenue - (717) 787-8201. *A copy of the sales tax license or proof of application is attached to this application.*

☐ According to the PA Department of Revenue rules and regulations, I have determined that my business is exempt from collection of sales tax.

PET POLICY

☐ **I have NO animals on or in the active food establishment premises nor will there ever be so long as I am registered as a Limited Food Establishment**. *(see page 9 for Pet policy)*

SECTION 4:

BUSINESS PLAN SUBMISSION

Provide, **in writing,** as an attachment to this application, your business plan. At minimum address the following, if applicable:

1) Ingredient suppliers (source)
2) Storage areas for equipment, food products and packaging
3) Types of equipment used in the production of the food
4) Production methods, including packaging methods (canning, overwrap, boxed)
5) Transportation methods to other locations or for delivery of products
6) How do you plan to sell the products? i.e., wholesale in state, wholesale out of state, internet, at a local farmers market, retail from the home, etc…
7) List the addresses of all locations from which you plan to sell your products--if you are retailing your product direct to the consumer. (ex: your home, a market, a roadside stand, local fire company, local fair)

SECTION 5:

PRODUCT LABEL SUBMISSION

Packaged products must have appropriate product labeling. Labeling must at minimum include:

1) Name of the product
2) Ingredients, listed from most to least by weight
3) Allergen declaration, if needed
4) Name and address of the manufacturer or distributor
5) Net Wt. or count; placement on the bottom 1/3 of the primary panel and no less than 8 pt. font

Bakery items made and sold directly to a Commonwealth consumer, by the baker, or their employee, (at the processing site or a satellite of the processing site such a farmer's market), do not require any labeling information directly on the products or any formal display of ingredients; **however, ingredient information must be available upon request.** Any baked goods not directly produced by the limited food establishment (purchased products) would require full labeling.

Any food products being sold interstate must meet requirements for Nutritional Labeling and will additionally be under the jurisdiction of the US Food and Drug Administration. You should contact them directly to discuss requirements or exemptions to nutritional labels. Information can be found at www.fda.gov and searching on "Small Business Nutritional Labeling Exemption."

SECTION 6:

LABORATORY TESTING

The following products will need to have product testing. This testing is to assure the safety of the product and that it is a non- TCS food. Additionally, some testing is used to confirm branding (ex, jam vs. jelly). See "Limited Food" Establishment Requirements for details.

NOTE: Additional testing may be required by the Department at any time to determine the safety and branding of the product. If you are unsure of what testing, if any, you must do, please contact your Regional Office for guidance. Testing must be done by you at any food laboratory of your choosing.

1) Acid, Acidified or Fermented Foods or Beverages: pH (acidity level)
2) Dressings/Sauces/Salsa: pH and Available Water (a_w)
3) "Moist" breads/cakes, and some pies: a_w and pH
4) Jams and Jellies: Potentially 'Soluble Solid' for product identity if requested.
5) Dehydrated Foods: pH and a_w
6) Any questionable product: pH and a_w

All laboratory test results must be submitted with this Plan Review Application. All products and product recipes must be tested. Any time a recipe changes or a new product is produced, additional product testing must occur. Producers should keep a copy of their product test results at their food establishments for review by the Food Inspector.

☐ **Not applicable, I do not believe my products require testing.**
☐ **I have submitted a copy of my product testing results, if applicable.**

SECTION 7:

PRODUCTION INFORMATION

TYPE OF ESTABLISHMENT (check which one applies)

☐ This kitchen is a personal use kitchen at a home
☐ This kitchen is a home-style kitchen on a residential property, but not a personal use kitchen
☐ This kitchen is a home-style kitchen not located on a residential property but another location (Fire company, church, American Legion, VFW, or other)
☐ This storage/warehouse establishment is on a residential property (& not a separate structure from personal use areas).

METHOD OF SALE (Check all that apply)

☐ Retail only ☐ Wholesale only ☐ Both Retail and Wholesale ☐ Internet Sales

TYPE OF FOOD PRODUCTION/HANDLING (Check all that Apply)

*****ONLY NON-TCS FOODS CAN BE MADE/ HANDLED BY A LIMITED FOOD ESTABLISHMENT.***

☐ Baked Goods	☐ Dry goods	☐ Dressings, Sauces	☐ Honey	☐ Beef/Meat Jerky
☐ Breads	☐ Cookies	☐ Acidified Foods	☐ Jams or Jelly	☐ Maple Syrup/product
☐ Cakes	☐ Pies	☐ Butters, Spreads	☐ Candy	☐ Beverage/Drink
☐ Vinegars	☐ Dried Herb	☐ Dehydrated foods	☐ Nut mixes	☐ Spices/seasonings
☐ Storage only/no handling		☐ Chocolate/fudge	☐ Other, list _____	

Describe your product(s): (specific types, styles, packaging methods) _____

_____

_____

_____

EMPLOYEE INFORMATION

_____# of anticipated employees (**include yourself in this number**)

Do you have an employee health policy? ☐ YES or ☐ NO

*An employee health policy establishes how to handle ill employees, including you, should they get ill or exposed to a potential foodborne pathogen. What will you do for an alternative production plan should you get sick? Do you understand what illness symptoms you may NOT work with? If you do not have a health policy prior to opening an employee health policy must be established, either **written or verbal**.*

ANTICIAPTED DAYS & TIMES OF PRODUCTION / OPERATION (check any that might apply)
Please list '*generally*' when you plan on processing / operating at this location.

☐ Monday Time _____
☐ Tuesday Time _____
☐ Wednesday Time _____
☐ Thursday Time _____
☐ Friday Time _____
☐ Saturday Time _____
☐ Sunday Time _____

SECTION 8:

WATER, SEWER, WASTE INFORMATION

WATER: The property is on, or will use:

☐ A public / municipal water supply. Supplier: _____ (ex: PA American Water Company) **And copy of water bill**

☐ A non-public / non-municipal / private water supply (example: well water). **A current water test must be provided. Your water must be tested at a Department of Environmental Protection (DEP) approved water testing laboratory of your choosing. Initial testing for Total Coliform (1 sample) and for Nitrate/Nitrite (1 sample) must be done and results provided.**

SEWER: The food establishment is on:

☐ A municipal/public sewage disposal system. Name of Sewage Authority: _____

☐ A non-public sewage disposal system (examples; Sand mounds, holding tanks). For on-lot sewage disposal systems, please contact the certified Sewage Enforcement Officer for your municipality and discuss if the current sewage disposal system is appropriate for your food establishment. This would not apply if the establishment is connected to an approved municipal supply, as listed above.

I contacted my municipality regarding my sewage disposal system on _____ (date). To the best of my knowledge my system is adequate for my Food Establishment and is functioning properly.

REFUSE:

The food establishment refuse (trash) collector will be: _____ (company name

SECTION 9:

This application and all other requested materials, as listed above, should be **submitted to RA-AGPlanReview@pa.gov or the Harrisburg Office via mail/fax**, as listed on page 8.

The Applicant understands and agrees that this document is an application for registration of a "limited food" establishment. The applicant understands and agrees that only a "proprietor" may obtain a Limited Food Establishment Registration; and that a "proprietor" may be a person, partnership, association, or corporation operating a food establishment within the Commonwealth of Pennsylvania. The applicant verifies that it is a/an (circle one): **person, partnership, association, corporation, LLC or LLP**; and that it is the "proprietor" of the Limited Food Establishment that is the subject of this application. The applicant verifies that all statements and information in this application is true and correct to the best of the applicant's knowledge, information and belief; and makes these statements subject to the penalties of 18 Pa.C.S.A. § 4904, relating to unsworn falsification to authorities.

Following a compliant inspection and payment of the registration fee you will be permitted to produce, and/or store, and sell your product. Your registration fee will be collected at the time of inspection. Your formal registration will be mailed to you within 60 days. Your inspection report will serve as your official approval until the registration is received.

Business Official / Owner Signature _____ PRINT Name _____

Date of Birth _____ Date _____

PROPRIETOR/OWNER TYPE: ☐ SOLE PROPRIETOR ☐ CORPORATION ☐ NON-PROFIT OR ASSOCIATION ☐ PARTNERSHIP ☐ LIMITED LIABILITY CO. (LLC) OR PARTNERSHIP (LLP)

IF A "COMPANY", A COMPANY OFFICIAL NAME & TITLE:

_____

LEGAL OWNER'S NAME BASED ON OWNER TYPE:

_____

(Examples: Mary Smith, Smith Inc., Mary's Little League Soccer or Smith LLC)

LEGAL OWNER MAILING ADDRESS (if different than above mailing address):

_____

Owner street number and name City State Zip code

(_____)_____ (_____)_____ _____

Owner phone number Owner fax number Owner e-mail address

All material must be submitted at least **60 days prior** to the **prior to production and distribution or sale of your food product**. Failure to provide all required information could delay your plan review.

Please check and sign you have included all required supporting documentation along with submission of the completed application.

Section 3:
I have attached the following supporting documents:

- ☐ Sales tax license or proof of application
  OR
- ☐ According to the PA Department of Revenue rules and regulations, I have determined that my business is exempt from collection of sales tax.
- ☐ I have NO animals on or in the active food establishment premises nor will there ever be so long as I am registered as a Limited Food Establishment.

Section 4:
I have attached the following supporting documents:

- ☐ Business plan (see section 5 for more details)

Section 5:
I have attached the following supporting documents:

- ☐ Labels (except exempt baked goods)

Section 6:
I have attached the following supporting documents:

- ☐ Laboratory testing results (if applicable, see section 7 to determine if this applies to you)

Section 8:
I have attached proof of municipal water supply OR I have contacted DEP and attached my approval letter OR I have attached my non-public water supply results and affidavit/DEP documentation. **Failure to provide written proof from DEP will result in denial of plans from this Department**

- ☐ Proof of municipal water supply (ex. A copy of a water bill)
  OR
- ☐ DEP Approval Letter for a non-community public water system
  OR
- ☐ Non-public water supply results

I have attached all required documentation for each section outlined above that are applicable to this plan review application. I have signed all applicable individual sections within the application. **Failure to provide documentation or sign all sections will result in a delay of processing and/or the application may be denied.**

Applicant Signature: _____

The Department of Agriculture will review the plans and notify you of its approval/disapproval within 15 business days. Once you receive your application approval, an opening inspection must be conducted prior to operating which your Food Inspector will schedule with you. Inquiries regarding your application status should be directed to **RA-foodsafety@pa.gov** or **717-787-4315**.

All material **must be fully completed** and returned with any necessary accompanying documentation to:

RA-AGPLANREVIEW@pa.gov

or mail / fax to:

Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
Attn: Plan Review
2301 N. Cameron St, Room 112
Harrisburg, PA 17110

Fax: 717-787-1873

Requirements for Home Processors
-- Limited Food Establishments --

The Department will allow some 'limited' types of food processing to occur in a "residential style kitchen," that may not meet the full regulatory code requirements, with the intent of the producer to offer these products for sale to the public. These processors are regulated under The Food Safety Act (3 Pa.C.S.A. §§5721 – 5737). Regulations under this Act include all federal regulations related to food and can be found in Title 21 of the Code of Federal Regulation (CFR's). CFR's can be accessed at www.ecfr.gov. In some cases, businesses may additionally be regulated under PA Code Title 7, Chapter 46, Food Code (if products are retailed direct to consumers from the business).

The term "limited food processor" or "residential-style kitchen" will be used throughout this document to refer to a home-style kitchen, residential style kitchen or a personal use kitchen, regardless of the location - on or off an actual residential property.

A Limited Food Establishment registration is NOT permitted in Philadelphia County.

Generally, the types of production that can occur in "limited food establishments" (whether an actual home-use kitchen or a kitchen designed in a residential fashion) are limited to foods that **ARE NOT** foods requiring Time/Temperature Control for Safety (TCS food) or formerly known as potentially hazardous foods (PHF).

"Time/Temperature Control for Safety Food" ***(TCS food)*** *means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. TCS Foods include any raw or heat-treated animal foods (examples include fluid milk, dairy products, eggs, meat & poultry, fish, shellfish, and edible crustaceans), heat treated plant food, raw seed sprouts, cut/ prepared fresh fruits & vegetables (including melons, tomatoes and salad greens), garlic-in-oil products, tofu & soy-protein foods, and perishable baked goods (including cream pastries, cheesecakes and custard pies).*

TCS foods can only be produced in a licensed / registered '*COMMERCIAL*' food establishment kitchen that meets the full regulatory code requirements, including separation from residential-use areas, and adequate plumbing fixtures. This does not specifically prohibit processing of TCS foods from a residential property, but the foods could only be produced in a second processing kitchen separate from the private home kitchen or any residential/personal use areas (separate entrances/ exits to food processing and storage areas are required), and that meets the full regulatory standards for a food establishment.

Canned foods that are not acid or acidified foods (LACF foods) also cannot be made from a Limited Food Establishment and can only be produced in a registered "COMMERCIAL' food establishment which has been approved for canning. These types of foods are highly regulated and require specialized equipment and filing of all canning processes with FDA (US Food & Drug Administration).

Bakery products, jams and jellies, acidified/fermented foods, dried mixes, and candy making are the most common types of foods from 'limited' food processors; however, other foods may be produced if determined to be a non-TCS food. This document will further discuss the common categories of home-processed foods. If you are unsure whether your product is a TCS food, you should discuss this with your Food Inspector. The Inspector may require you to have "questionable" products laboratory tested for pH and water activity (a_w).

Limited food processors generally cannot comply with the full extent of the regulations, but they do have certain requirements and limitations to follow to meet the food safety intent of the regulation.

General rules for all products are as follows:

- **Pet Policy -**
  No animals/pets are permitted in the home *at any time* if the personal home kitchen is used. This would apply to residential-style kitchens, in any other location as well.
  However, Limited Food Establishment (LFE) registration may be allowed if a home is designed in such a way that the area where food is processed and stored is not EVER accessible by a pet, even when not actively processing. The processing and storage area (kitchen) must be physically separated from the part of the home where pets are allowed (a physical barrier, such as a fully-closing door, is required. Baby gates and removable barriers are not acceptable), AND the area must have a separate exit/entrance so the operator can bring in ingredients and take out finished products without ever entering any areas where pets have access.
  Pet shall include, but is not limited to; dog, cat, bird, small animal such as a rabbit or ferret.
  Pet shall not include: fish, caged reptile, caged hamster or similarly confined animal, so long as the caged animal is not located in, or in close proximity to, areas used specifically for the LFE.

- **Children** are not permitted in the kitchen area during food processing for the business.
  There are no mandated age limits for operators and or employees in a limited food establishment. However, members involved must demonstrate basic food safety knowledge and adhere to good hygiene, processing and sanitary practices.

- The **water** supply must be from an approved source. Private sources (not regulated by DEP) must be tested as per the following PDA protocol:
  - *Initial testing for Coliform (1 sample) and Nitrate/Nitrite (1sample)*
  - *Continual testing for Coliform - Annually*
  - *Continual testing for Nitrate/Nitrite will be based on initial results.*

- Department approval *does not imply* that the business will be in compliance with any local **zoning** or ordinances. All businesses should confirm and receive approval from their local authority for zoning and other code enforcement issues, such as sewage disposal.

- Registration and **fee** ($35.00) by the Department of Agriculture are required. A registration fee exemption exists for Honey Processors if the honey is produced and processed on the same farm. Honey Processors will still be required to register and be inspected if selling off site of the processing farm.

- All **ingredients** must be separate from those for personal use (separate shelves, separate cupboards, etc…) and must be properly labeled, stored and protected. Proper storage includes using food-grade containers that keep pests out and maintaining temperature control to prevent spoilage.

- There must be restricted use of the residential-style kitchen during any business-related food processing. Home food preparation and commercial food processing operations cannot be conducted at the same time. A "dual-use" kitchen requires you to carefully schedule your time so that private and business activities do not conflict.
- Processors must adhere to good personnel hygiene standards and maintain sanitary conditions and practices in the kitchen and/or any storage areas.

- Any required laboratory **testing** of food products is arranged for and paid for by the producer. Although not a comprehensive list of laboratories capable of food testing, a listing of commercial laboratories is available on our web site at https://www.agriculture.pa.gov/consumer_protection. Select 'Laboratory' in the right-hand margin then find a link to "PA Approved Commercial Laboratories" at middle of webpage.

- Products must be properly **labeled** as follows (*with some labeling exemptions for baked goods*):
    - *Statement of Identity – the common or usual name of the food product*
    - *Name and address of manufacturer/processor*
    - *Ingredients listed in decreasing order by weight (including sub-ingredients)*
    - *Allergen declaration if needed*
    - *Net weight or unit count.*

- **Nutritional labeling** must be included on food products being shipped / sold in interstate commerce (across state lines). Most Limited Food Establishments will qualify for a small business exemption from nutritional labeling requirements but must apply with FDA. Information and the exemption application can be found at

  http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm2006867.htm

- Any labeling for **health claims** such as Low Fat, Sugar Free, Gluten Free, Dairy Free, and similar, must be accurate and be supported by manufacturer's labeling of sub ingredients or through product testing. By adding a claim to your label, you may be required to comply with Nutritional Labeling requirements. Contact FDA as noted in #11 above.

- Processors must comply with all applicable state and federal laws and regulations.

- Under the Food Safety Modernization Act (**FSMA**), food facilities which wholesale may be required to register with FDA (section 415 of the FD&C Act (21 U.S.C. 350d).
  There are certain exemptions for businesses operated from a private residence, and for businesses whose primary sales are retail (direct to consumers).

  For more information contact FDA at 1-800-216-7331or 301-575-0156 or visit their website at: *http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm*

**** This is not a complete list of the types of foods that may be allowed to be made in a limited food establishment. Products are evaluated individually, as to whether or not they can be produced in a limited food establishment.**

BAKED GOODS

Baking is the most common type of food processing conducted in a limited food establishment. Traditional bakery items produced include but not limited to cakes, breads, bagels, cookies, rolls, muffins, brownies, biscuits/ biscotti, tortilla and most fruit pies/ pastries, etc.

Perishable baked goods (TCS food) are NOT allowed to be prepared in the limited food establishment and may include items such as cheesecakes, pumpkin pies, cream/custard or meringue pastries/ pies and desserts, pudding prepared from a mix or scratch, or any food item that has sufficient moisture, high pH (low acidity, pH>4.6) and/or ingredients that will support the growth of pathogenic microorganisms. TCS foods may also include baked good containing meat or cheeses.

Generally, any product which is not shelf-stable at room temperature and requires refrigeration after preparation would be considered TCS food. Most baked goods do not require testing; however, **baked goods in question, shall be tested for pH and Available Water (a_w) by the producer. Evaluation of the product will be made by the Food Inspector following the submission of the results.**

Bakery items made and sold directly to a Commonwealth consumer, by the baker (or their employee), do not require any labeling information directly on the products or any formal display of ingredients; **however, ingredient information must be available upon request.** Any baked goods not directly produced by the limited food establishment (purchased products) would require full labeling.

Items sold at a retail facility, not owned or operated by the baker; require one of the following forms of labeling:

(1) Packaged Bakery Product must have all required labeling information on the package.

(2) Loose/ Bulk-Displayed Bakery Product must have all required label information posted by the display.

(3) Bakery Products sold at retail facilities, for consumption on the premises, such as a restaurant, require that the label information be available to the consumer upon request.

Any item labeled with a claim such as Gluten Free, Dairy Free, Organic, Sugar Free or similar must be able to substantiate the that claim through manufacturer's labeling of sub-ingredients or through product testing. The Code of Federal Regulations (CFRs) has specific guidelines regarding under what circumstances these claims may be made. Use of claims may require a nutritional facts panel.

JAMS, JELLIES & SIMILAR PRODUCTS

Producers of jams and jellies must have written recipes/ formulas and procedures.
No testing is required if producers of jams/ jellies are using the standard recipes contained in one of the following guides:

1. *The Ball Blue* Book – *Guide to Preserving.*
2. *USDA Complete Guide to Home Canning - National Center for Home Food Preservation.*
3. *A University Extension Service: e.g. http://extension.psu.edu/food/preservation*

However, anytime the standard recipe is altered or a new recipe is developed, the final product of each recipe must be reviewed and analyzed by a food testing laboratory for **soluble solids (Brix)** to identify if the product is correctly identified for their Standard of Identity (*21 CFR 150*).

- 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. Jam, jelly and preservatives not meeting a proper Standard of Identify may need evaluated further.

The soluble-solids content of the finished jelly or jam may not be less than 65 percent (65% Brix), as determined by the method prescribed in the "Official Methods of Analysis of the AOAC" 13th Ed. (1980), section 31.011, under "Solids by Means of Refractometer--Official Final Action,"

- **Fruit jellies** have 45 parts by weight of the fruit component to each 55 parts of the sweetener solids (45:55). The finished soluble solids content of a jelly is not less than 65%.
- **Fruit preserves and jams** are divided into two groups, generally the berries and the pomes.
  - *Those made from the berry group require 47 parts by weight of the fruit component to 55 parts of the sugar (47:55).*
  - *Those made from the pomes require 45 parts by weight of the fruit component to 55 parts of the sugar (45:55).*

  In both cases the finished product is not less than 65% solids.
- Fruit butters, preserves, artificially sweetened fruit jelly, each have specific standards of identity and soluble solid requirements.
- Conserves, Marmalades, and "Spreads" do not have standards of identity, and do not require soluble-solids testing.

REFERENCE & RESOURCES

- Fruit butter, Jellies, Preserves and related products (21 CFR Part 150): *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=150*
- USDA complete guide to Home Canning - National Center for Home Food Preservation: *http://nchfp.uga.edu/publications/publications_usda.html*
- The Ball Blue Book – Guide to Preserving: *http://www.freshpreserving.com/recipes/*
- *Penn State Extension (Home Food Preservation):*

  https://extension.psu.edu/food-safety-and-quality/home-food-safety/food-preservation

BEVERAGES / DRINKS / JUICES

Some beverages and drinks can possibly be made from a limited food establishment. This may include Root Beer, Lemonade, Lemon Ice 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 fermented beverages should aim for a pH level of 4.2 or below. Fermented drinks that are 'bottled' or 'canned' need some type of 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 limited processors. **This category does not include freshly brewed coffee and tea. They are considered TCS food due to their high pH (>4.6).**

(*) See "Guidelines for brewing/bottling Kombucha" for more information. The guidance document can be found HERE under Publications Tab.

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

❖ JUICE – Producers of Juice who sell RETAIL Only:

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).

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 a HACCP system. 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:

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 who produce from a limited food establishment must have their products tested for pH to determine if the product is a non-PHF/non-TCS food. Only products with a pH of 4.6 or below can be made from a limited food establishment.

Product may only be sold direct to the consumer from the production site or from a satellite of the production site, such as a farmers 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.

❖ **JUICE – Producers of juice who Sell WHOLESALE:**

Except for juice produced for retail sale only, 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. Any juice of this type must be pasteurized or have an approved and verified 5–log reduction of pertinent microorganism and be operating under a HACCP plan. Juice of this nature can typically *NOT* be produced in a limited food establishment. Residential-Style Kitchens would not typically have the required equipment to obtain a pathogen reduction.

CANNING OF ACID/ACIDIFIED/FERMENTED FOODS

Limited Food Establishment Producers 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 Available Water (a_w) may also be tested). Examples of 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, pickles, green olives, etc.) or,
- ✓ Acidified foods (e.g. salsa, chow-chow, pickled beets/ vegetables, hot sauces, and BBQ sauce).

Definitions:

- ***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 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.

Further, *if your final equilibrium pH is between 4.2 and 4.6,* you must have your product flow, recipe and process evaluated and approved by a ***Process Authority*.***

(A process authority is defined as a qualified person or entity who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.)

❖ 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 your final equilibrium pH is between 4.0 and 4.6*, you must have a properly calibrated ***pH meter*** and check the pH of every batch produced.

For a list of subject matter experts (SME) and process authorities, click HERE.

- *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 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.

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.

- *If a food is homogeneous*, 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).
- *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. 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

For guidance on how to purchase a pH meter, please visit Cornell University's fact sheet on *purchasing a pH meter*. 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.

❖ THERMAL PROCESS (COOKING) & 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, 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 achieve on the container.
   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.
   Processors may choose other scientifically approved time/temperature combinations.
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.

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.

❖ OTHER 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 and sanitized
- All labeling requirements on the containers must be met (see labeling section pg.5).

NOTE:
Processors wishing to sell their products interstate (which include internet sales), or using ingredients obtained from interstate 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 may 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, especially if you intend to sell products in interstate commerce. For more information contact FDA at 1-800-216-7331 or 301-575-0156.

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 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 in syrups.

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

CANDY

Most types of candy can be made in a limited food establishment. These would include but not limited to fudge, caramels, truffles, cotton candy, lollipops, chocolates, tortes, hard candy, rock candy and others. All labeling requirements on the containers must be met. Chocolate covered fruits may not be made from a limited food establishment unless the fruit utilized has a pH of 4.6 or below, such as most apples and strawberries (*fruit must be in its whole intact state, with no cutting or chopping occurring*).

Any fruit in question may be required to have a pH test performed to determine pH levels.
No product testing is required for most candy.

OTHER FOODS

Dry goods: cereals, coffee/tea, spices/seasonings, dry herbs, dry pasta, nuts/seeds and mixes, etc.

Dehydrated foods: dried fruits/vegetables dried Herbs, beef/meat Jerkies, etc.

Freeze Dried foods: Freeze drying may be permitted; however, final product testing for Water Activity is required to verify the product is non-TCS. Written procedures must be submitted with lab testing if the food to be freeze dried would be a TCS food prior to the process, if the food has a naturally occurring pH above 4.6, or if it would be a TCS food when subjected to a cooking process.

Condiments: honey/maple syrup & products, ketchup, mustards, vinegars, nut butters/spreads, dressings, sauces, oils excluding garlic/oil mixtures, etc.

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.

Getting Started with Your "Limited Food" Establishment Business

1. Contact your local municipality (city office, township office, city or borough office, etc.) to ensure that local ordinances and zoning requirements allow operation of a food business from a residential property, from a home, or from any other location you have selected.

2. If the production site has a non-public water supply (well or similar), you must initially have the water tested for **Coliform and Nitrate/Nitrite** (see testing protocol above). Choose an approved DEP (Department of Environmental Protection) water testing laboratory in your area. Water test results should be submitted with your Plan Review Application. If the processing site is on a municipal or public water supply, you need not do any water testing. For a complete list of PD-DEP approved Laboratories, ***click here***.

- If the food product you are making requires any laboratory testing, as listed herein, this testing should be submitted with your Plan Review Application or prior to the first inspection. Choose any local laboratory conducting food testing. If you are unsure if your product should be tested contact your local regional food inspector to discuss. A listing of some PA approved commercial laboratories is available on our web site at https://www.agriculture.pa.gov/consumer_protection. Select 'Laboratory' in the right-hand margin then find a link to "PA Approved Commercial Laboratories" at middle of webpage.

3. **Fill out the required *"Application for Limited Food Establishment Registration"* and return it with all necessary accompanying documentation to RA-AGPlanReview@pa.gov or the Harrisburg Office via mail/fax**, as listed on the cover letter. Please allow 4-6 weeks for processing of your application from the date of submission.

If you are going to sell your product at a retail satellite location (farmers market, roadside stand, fair, etc…) or create a retail store at the processing site, this retail site may additionally need a Retail Food License with the Department *(or a Local Health Jurisdiction**)*, but potentially may be exempt from fees. A *Retail* or *Farmer Market Vendor* Plan Review Packet (available on request or on our web site) will need to be filled out for those retail locations.

Visit https://www.agriculture.pa.gov/consumer_protection to find the application packets for Retail Food Facilities and Farmer Markets under their respective programs (under Forms Tab).

If using a shared commercial kitchen (incubator), you still need your own registration even though the same kitchen is used by other food business owners at different times of operation. A completed Agreement must also be submitted to your regional office along with the application. The Shared Facility Agreement form is can be found in the Limited Food Establishment program under Forms Tab.

****** Retail Food Facilities located in Local Health jurisdictions would need to obtain their Licenses/ permits from these Local Health Departments directly. To determine whether your retail location is under a local jurisdiction, click here and find the "Local Health Department" list under Publications Tab.

If approved, you will be contacted by the regional Food Inspector and/or Supervisor with follow up instructions. If disapproved, you will receive a written letter explaining why your plans have been disapproved, and you may re-submit at any time thereafter.

4. When all prior items are complete and approved, contact the Food Inspector to make arrangements for inspection. At the time of inspection, your inspector will discuss with you the standards and good manufacturing practices expected of your business, labeling and testing requirements, if applicable, and any other necessary food safety information. At the conclusion of your inspection, if satisfactory, your Food Inspector will collect your $35.00 registration fee and you will be ready to begin your business.

REFERENCES & OTHER RESOURCES

- PA Department of Agriculture's Bureau of Food Safety Website: https://www.agriculture.pa.gov/consumer_protection
- Pennsylvania Food Safety Act (3 Pa. C.S.A. §§5721 - 5737).
- FDA Food Facility Registration: *http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm*
- FDA Food Labeling Regulations (21 CFR Part 101) *http://www.gpo.gov/fdsys/pkg/CFR-2008-title21-vol2/xml/CFR-2008-title21-vol2-part101.xml*
- Penn State Food Safety & Processing: https://extension.psu.edu/food-safety-and-quality
- Penn State University Extension Offices listed by county: *http://extension.psu.edu/counties*
- FDA Regulations, Registration & Process Filing Information
- FDA Guidance for Processors of Acidified & Low-Acid Canned Foods

- **Trademarks** - How to register a trademark with the United States Patent and Trademark Office *http://www.uspto.gov/trademarks/basics/index.jsp*

- FDA Food Labeling & Nutrition Information: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm

FDA FSMA Preventive Controls (PC) for Human Food

- The Pennsylvania Department of Agriculture (PDA) will adopt the new federal regulations as dictated by the Food Safety Act (3 Pa. C.S.A. §5733(f)) and will enforce all applicable provisions as of the effective compliance date. As Pennsylvania regulation, all PDA registered firms will be expected to comply with the applicable portions of the PC Rules regardless of FDA registration status, unless specifically exempted in the Rule. During inspections, PDA will evaluate whether a limited food establishment is affected by any portion of the rule to enforce the applicable required provisions.

- Most PDA limited food establishments may be qualified for the modified PC requirements which apply to:
  - very small businesses (less than $1,000,000 in annual sales); OR
  - food establishments having less than $500,000 in gross annual sales (3 years average) ***AND*** the majority of the food is sold directly to a "qualified end-user**".

    *** Qualified end-user is defined as a Consumer (who cannot be a business), or a Restaurant or Retail Food Facility (whose main function is to sell food directly to consumers) AND that is located in the same state or within 275 miles of your food establishment.*

- Visit https://www.agriculture.pa.gov/consumer_protection and select FSMA program to learn more about Preventive Controls for Human Foods requirements.