



pennsylvania
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY & LABORATORY SERVICES

APPLICATION PACKET FOOD ESTABLISHMENT REGISTRATION

FOOD ESTABLISHMENTS

Manufacturing, Processing, Distribution, Warehousing, Wholesale

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Enclosed are the necessary forms and applications for obtaining a Registration from the Pennsylvania Department of Agriculture. Please be advised that according to The Food Safety Act of 2010 (3 C.S. §§5721 – 5737), “...it shall be the duty of every person operating a food establishment within this Commonwealth to register...” A food establishment applicant may be a food processor/manufacturer, warehouse, distribution center or wholesaler.

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FOOD ESTABLISHMENT

SECTION 3:

ESTABLISHMENT INFORMATION

TYPE OF ESTABLISHMENT: (Check Classification and then Sub-classification)

WAREHOUSING / DISTRIBUTION

Type of storage (sub-classification): Dry Refrigerated Frozen

Briefly describe the product(s) you will be holding/storing for distribution at this location:

Are you storing any fish, seafood or fishery products at this location? YES NO

MANUFACTURING / PROCESSING

Type of Operation (Sub-Classification):

- | | | | | |
|---|---|---|---------------------------------------|--------------------------------|
| <input type="checkbox"/> Acid/Acidified Food | <input type="checkbox"/> Low Acid Canned Food | <input type="checkbox"/> Aseptic Packaging | <input type="checkbox"/> Bakery | <input type="checkbox"/> Candy |
| <input type="checkbox"/> Cereal | <input type="checkbox"/> Egg Plant | <input type="checkbox"/> Fruits & Vegetables | <input type="checkbox"/> Grain Mill | <input type="checkbox"/> Honey |
| <input type="checkbox"/> Juice/Cider | <input type="checkbox"/> Beverage (Alcoholic) | <input type="checkbox"/> Beverage (Non-Juice/Non-Alcoholic) | <input type="checkbox"/> Seafood | |
| <input type="checkbox"/> Snack foods | <input type="checkbox"/> Bottled Water | <input type="checkbox"/> Maple products | <input type="checkbox"/> Jams/Jellies | |
| <input type="checkbox"/> USDA-inspected foods | <input type="checkbox"/> USDA-exempt Meat/Poultry | | | |
| <input type="checkbox"/> Other: _____ | | | | |

Briefly describe the product(s) you will be manufacturing/processing at this location:

PLANS REVIEW:

Although not required by Law, new Food Establishments that would like the Department to review and provide comments on plans for their establishment, may voluntarily submit a blue print – or hand-draw sketch – of the proposed food establishment layout and/or a listing of proposed equipment

FOOD SAFETY SYSTEMS AVAILABLE:

Check all applicable boxes to indicate the food safety systems you will have implemented in the establishment:

Hazard Analysis Critical Control Points (HACCP): Yes (mandatory) Yes (voluntary) No

Modernized GMPs (to include): Sanitation SOPs Employee Hygiene & Health SOPs Training

Pest Control: (Company name): _____

Third Party Audit: (Company name): _____

FSMA Food Safety Plan: YES NO Exempt

Process Controls **Allergen Controls** **Sanitation Controls** **Supply-Chain program** **Recall Plan**

Other Formal Food Safety Systems: Specify: _____

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HEALTH POLICY:

Do you have an employee health policy? YES NO

This is NOT an employee medical examination requirement. An employee health policy establishes how to handle ill employees, including you, who may be working in the food establishment. It is an understanding of when to exclude or restrict food handlers who are ill with certain symptoms. If NO is checked, prior to opening an employee health policy must be established, either in writing or verbal, and presented to every employee of the establishment.

ADDITIONAL INFORMATION:

- Projected food stored / manufactured:** _____ %
- Annual gross sales:** _____
- Projected Wholesale Activities:** _____ %
- Projected Interstate Commerce:**
 - *Incoming ingredients:* _____ %
 - *Shipped finished Products:* _____ %
- Number of full-time equivalent Employees:**
 - *Onsite:* _____
 - *Business Wide (including any subsidiaries and affiliates):* _____
- Establishment size (sq. ft.):** _____
- Is the food establishment registered with FDA?** YES NO Exempt

SECTION 4:

WATER, SEWER, WASTE INFORMATION

Issuance of a Food Establishment Registration in no way implies that this Establishment is compliant with any other state or local rules relating to water, sewer, zoning or building codes of any kind. It is the applicant responsibility to assure they are compliant with all other state or local rules and regulations.

WATER:

You must contact the Department of Environmental Protection (DEP) to determine if your facility qualifies as a public water system (PWS). If DEP determines your facility qualifies as a public water system, then the water supply must be approved by DEP. **Written documentation** must be provided including your assigned Public Water System (PWS) ID# and **approval letter** from DEP. If DEP determines your facility does **NOT** qualify as a public water system, **written documentation** from DEP must be provided and **current water tests for Total Coliform (4 initial samples in 24 hours) and 1 initial sample for Nitrate/Nitrite**.

The facility is using:

- A municipal (community) water supply.
Provide name of municipal water supplier: _____ (ex: Pa American Water) **AND copy of water bill.**
- A non-community water supply that is not owned/operated by the facility.
Provide name of the regulated water supplier and its Public Water System ID#: _____ (ex: The Shopping Plaza, Public Water System ID#: 1111111)
- A non-community public water supply regulated by Department of Environmental Protection (DEP). Provide Public Water System (PWS) ID#: _____ **AND DEP Approval Letter**
- Other / Private water supply (ex: well water). **Provide Affidavit from DEP AND water supply test results.**

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SEWER: The Establishment is using:

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.

REFUSE:

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

List any other Refuse or waste collection companies (ex: grease collection, food scraps etc...):

DAYS & TIMES OF OPERATION: Check anticipated days and time the facility will be operational:

Monday Time _____
 Tuesday Time _____
 Wednesday Time _____
 Thursday Time _____

Friday Time _____
 Saturday Time _____
 Sunday Time _____

ZONING AND OTHER CODES

Issuance of a Food Establishment Registration in no way implies that this Establishment is compliant with any other state or local rules relating to water, sewer, zoning or building codes of any kind. It is the applicant responsibility to assure they are compliant with all other state or local rules and regulations.

I have verified that the Establishment is compliant with all Local Zoning and all Building Codes as required. 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/registration.

A license to collect PA State sales tax has been obtained or applied for. For information on applying for a PA State sales tax license, contact the Pennsylvania Department of Revenue - (888) PATAXES or <https://www.pa100.state.pa.us/>

OR

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

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SECTION 5: ALL APPLICANTS READ AND SIGN

The Applicant understands and agrees that this document is an application for Registration of a wholesale manufacturing / processing and/or warehouse / distribution food establishment operation. The applicant understands and agrees that only a "proprietor" of this operation may obtain the registration; and that a "proprietor" may be a person, partnership, association or corporation operating the food establishment within the Commonwealth of Pennsylvania. The applicant verifies that they are the "proprietor" of the food establishment that is the subject of this application as indicated on this application. By signature on 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.

INDIVIDUAL PERSON:

Signature

Legibly Print Name

Date

Date of Birth

PARTNERSHIP:

Signature – General Partner

Legibly Print Name

Date

Date of Birth

Signature – General Partner

Legibly Print Name

Date

Date of Birth

CORPORATION OR ASSOCIATION / NON-PROFIT ENTITY:

Name of Corporation or Non-Profit Entity

Name of current CEO/President/or similar

Official Title

Date of Birth of CEO/President/or similar

Signature of Corporate / Association / Non-Profit Official

Official Title of Signatory

Legibly Print Name

Date

LIMITED LIABILITY COMPANY (LLC) OR LIMITED LIABILITY PARTNERSHIP (LLP):

Name of LLC or LLP

Name of Senior Official/General Partner, or Similar

Official Title

Date of Birth of Senior Official/General Partner, or Similar

Signature – Member

Date

Signature – Member

Date

Legibly Print Name

Legibly Print Name

LEGAL BUSINESS NAME (if different than establishment name): _____

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

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All material must be submitted at least **60 days prior** to construction, remodeling, alteration of a facility, change in type of food operation, new ownership or the preparation/sale of foods from a food establishment AND at LEAST 60 days prior to opening. 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 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 **AND** affidavit / DEP documentation

Section 4:

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 certify the facility is compliant with sales tax licensing.

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: _____

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The Department of Agriculture will review the plans and notify you of its approval/ disapproval. Please allow **4 – 6 weeks** for processing. Once you receive your approval, notify your Food Inspector or regional office at least **ten (10) days prior** to production to arrange an inspection. Inquiries regarding your application status should be directed to 717-787-4315.

DO NOT SEND ANY MONEY WITH THIS APPLICATION.

*There are NO fees associated with this Application. Registration fees will be collected upon a compliant inspection.
Initial registrations and annual renewals are \$35.00 made payable to the “Commonwealth of PA”*

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

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APPLICATION INSTRUCTIONS FOR FOOD ESTABLISHMENTS

Food Processing, Manufacturing, Warehousing, Distribution, Wholesale

PREPLANNING

1. Review thoroughly a copy of the rules and regulations pertaining to the specific type of food establishment planned prior to and during preparation of plans. Applicable law is Title 3 of the Consolidated Statutes, Chapter 57, Subchapter B, Food Safety Act.
2. Discuss any unanswered questions regarding registration and requirements for plan review with the Plan Review Program Specialist.
3. **Complete an application for “Food Establishment Registration”** which is to be submitted at **least 60 days** prior to opening.
4. **DO NOT** begin construction, remodel or conversion of the establishment prior to submitting acceptable plans and prior to receiving approval of the submitted plans from the Department. New owners and change of ownerships are required to apply for a registration and gain approval *prior to* preparation and distribution of foods.
5. All local planning, zoning, building, fire etc., codes must be considered as well as requirements of the Department of Labor and Industry, Department of Environmental Protection, and the Liquor Control Board, if the establishment will also be regulated by these agencies. Issuance of a Food Establishment Registration in no way implies that the Establishment is compliant with any other state or local rules relating to water, sewer, zoning or building codes of any kind. It is the applicant responsibility to assure they are compliant with all other state or local rules and regulations.

SECTION 1:

PART A: Enter the Date the Establishment is anticipating opening or beginning production or when the legal change of ownership will occur. Please select in this section which best describes your establishment.

PART B: Please select the box that best describes why you are filling out this application. Are you a new owner looking to get a new registration? Are you taking over an existing operating establishment (change of ownership)? Are you remodeling your registered establishment or significantly changing your business? Whichever best describes, please select. If none of these choices seems to describe why you are applying, select “other” and note why you are applying for a Food Establishment Registration.

SECTION 2:

This section will capture information about your establishment. Please fill in this section completely. The physical address of the food establishment should be the 911 address. PO Boxes cannot be used as a physical address, but can be captured as the mailing address.

SECTION 3: Establishment Information

This section will collect the days of the week and time in which the establishment is operating. Please list as best as possible your establishment operating days. If your operation times vary or fluctuate greatly, please make a best guess as which days of the weeks and times you plan on operating/processing.

Type of Establishment: This section addresses information regarding the classification and sub-classification of your establishment. Please indicate the type of establishment by checking the appropriate box and then the type of storage and or operations conducted at the establishment. If the type of operation is not listed, check “other” and specify your operation using your own words. Please give more details about the products you will be manufacturing/ processing and or holding for distribution at this location.

Plan Review: Although not required by Law, New Food Establishments that would like the Department to review and provide comments on plans for their establishment may voluntarily submit a blue print – or hand- draw sketch – of the proposed food establishment layout and/or a listing of proposed equipment.

Food Safety Systems Available

Check all applicable boxes to indicate the food safety plans or programs you will have implemented in the establishment. Most of these plans are now required under the new current GMPs and HARPC Final Rule requirements as set forth in 21 CFR Part 117 as applicable.

To learn about the FDA’s new FSMA Preventive Controls for Human Food, visit:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

Seafood and Juice food establishments must have training related to HACCP and have developed HACCP plans to be compliant with the regulations.

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Information about Seafood HACCP: <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006764.htm> Information about Juice HACCP: <http://www.fda.gov/food/guidanceregulation/haccp/ucm2006803.htm>

Employee Health Policy:

Even if the owner is the only employee please address how the establishment will handle ill employees, whether someone may work while ill and at what point restriction or exclusion of the person from the food establishment should take place. This policy does not need to be a written policy. This Employee Health question is asked to bring your attention to this very important issue. Your Inspector, as part of a routine inspection, will discuss your policy with you.

Additional Information

- Indicate the % of Wholesale activity engaged by the established business.
- An interstate commerce is established when a food from the establishment is shipped interstate OR any ingredients that will come into the establishment come in through interstate channels. Indicate the projected % of finished product that will be distributed interstate AND the projected % of ingredients that will be received via interstate.
- Provide the number of all employees at the establishment (including temporary and seasonal employees).
- Provide the establishment's square footage size (Total).

SECTION 4: Water, Sewer, Waste Information

This section will capture the information about the water supply you are using, your waste water disposal and your trash collection.

Water Supply: Please select the type of water supply you are using at the establishment. Building owners/operators may need to supply you this information if you are using their water supply. All water supplies are either PUBLIC or NON-PUBLIC.

Public or Municipal Water Supplies:

Public supplies are those regulated by DEP. Some "wells" and/or Non-municipal water supplies are additionally regulated by DEP as Public Supplies. **You must contact DEP (717-783-2300) to determine if your water supply should be regulated by that Agency.** You may obtain your water from any DEP regulated water supply.

For Municipal- Public water sources, please list the name of the Public Water Supplier. For example: Pennsylvania American Water.

For Non-Municipal Public water supplies, please provide proof from DEP that your water supply has been approved as a Public supply, such as your assigned Public Water Supply (PWS) number.

Non-Public Water Supply:

If it has been determined that you are utilizing a Non-Public, Non-DEP regulated water supply, you shall then conform to the construction, maintenance, and operation requirements established for a transient non-community water system as defined in 25 Pa. Code Chapter 109. **Those water systems will need to submit initial testing of the water supply to include, four sequential Total Coliform samples and one nitrate/nitrite sample to PDA prior to licensing or registration.** Ongoing testing of the water supply for non-public systems (non-DEP regulated), shall continue to be performed at a frequency determined based on the risk category of the food establishment (high/medium), the use of water as an ingredient and/or the initial results of nitrate/nitrite testing.

Exception: Maple Syrup, Honey and Apple Cider processors, although medium risk, may follow the following low risk testing protocols:

- Initial testing for Coliform (1 sample) and Nitrate/Nitrite (1 sample)
- Continual testing for Coliform - Annually
- Continual testing for Nitrate/Nitrite will be based on initial results.

This water testing will most likely be provided by the owner of the physical property.

Please consider the following...

- Approval of the water supply shall be based on satisfactory compliance with the latest edition of the Public Water Supply Manual for Construction Standards and Title 25, Chapter 109 for Water Quality, Pennsylvania Department of Environmental Protection (DEP).
- If your establishment is on a well and determined to be 'public', it must be approved by DEP, Department of Environmental Protection (717-783-2300). Written documentation of approval must be provided.

Sewage Disposal: On the application, please check which applies.

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If your establishment is utilizing a municipal sewage system, you need only supply the name of the sewage enforcement municipality.

For establishments NOT using a municipal/public sewer: It is the responsibility of the owner/applicant of the Establishment to contact the local Sewer Enforcement Officer for their municipality to review whether or not the current on-lot sewage system is approved and adequate for the use of the establishment. Note: Approval of all sewage disposal systems will be based upon satisfactory compliance with Chapter 71 and 73 of this title, The Clean Streams Law, Act of June 22, 1937, P.L. 1987, as amended (35 P.S. §§691.1 et seq.) and/or as determined by the local governing sewage enforcement agency or local Sewer Enforcement Officer (SEO).

Refuse, Recyclables & Returnable: On the application, please check any that apply.

- If refuse is to be disposed of on site at the establishment the refuse company name need only be supplied. *Disposal of garbage and refuse shall conform to the Solid Waste Act, Act of July 31, 1968, P.L. 788 (No. 241), Section 6, (35P.S. Section 6006) and the regulation adopted pursuant thereto, Chapter 75 of this title (relating to Solid Waste Management).*
- If disposal is to take place off site, list the name of the collector and location of disposal site.

Please select whichever boxes may apply.

Zoning and Building Code information may need verified with the property or building owners. By signature on this application, you are confirming that you have contacted local authorities to review compliance with the applicable local codes.

Sales Tax License information can be obtained with the PA Department of Revenue at (888) PATAXES or <https://www.pa100.state.pa.us> Please check which box best describes your tax situation.

SECTION 5:

Please read the remainder of this section and fill in the appropriate 'ownership' block with signatures.

There are NO fees associated with this Application. Registration fees will be collected upon a compliant inspection. Initial registrations and annual renewals are \$35.00 made payable to the "Commonwealth of PA".

ADDITIONAL INFORMATION:

The Food Safety Act of 2010 (3 C.S §§5721 - 5737) states ***"...it shall be the duty of every person operating a Food Establishment within this Commonwealth to register...."*** with the Department. Registration shall occur prior to the processing, distribution or sale of food, and food establishments *may* label their products with the approved abbreviation ***"Reg. Penna. Dept. Agr."***

❖ **FDA REGISTRATION**

Some food facilities are required to register with the U.S. Food and Drug Administration (FDA) under the 2002 Bioterrorism Act. Generally, if you manufacture, process, pack, or hold food for consumption in the US, then you meet FDA's definition of a "facility," and are required to register unless exempt under 21 CFR 1.226. To learn more about who must register their facilities with FDA under the Bioterrorism Act of 2002 visit FDA website at:

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

❖ **FDA FOOD SAFETY MODERNIZATION ACT (FSMA)**

The Food Safety Modernization Act (FSMA), which became law in 2011, requires facilities that manufacture, process, pack or hold human food and that must register with FDA under 2002 BT Act to ALSO follow the Preventive Controls Rule's new food safety requirements found in 21 CFR Part 117.

In broad terms, the FDA's new rule governing human food facilities (aka "the ***Preventive Controls Rule***" or "***PC Rule***") requires domestic and foreign food facilities to follow updated good manufacturing practices (***cGMPs***), and establish and implement a Hazard Analysis and Risk-Based Preventive Controls for human food.

The Preventive Controls for Human Food rule is now final and compliance date for some firms begin as early as September 2016.

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For more information about the FDA's FSMA Preventive Controls requirements, visit the following:

- www.fda.gov/fsma
- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>
- <https://extension.psu.edu/fsma>



As Pennsylvania regulation, all PA Department of Agriculture (PDA) registered firms will be expected to comply with at least some portion of the Preventive Controls Rule regardless of FDA registration status, unless otherwise specifically exempted in the Rule.

❖ FDA FSMA TECHNICAL ASSISTANCE NETWORK (TAN)

The FDA Food Safety Modernization Act (FSMA) Technical Assistance Network is now operational and providing technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The Technical Assistance Network will address questions related to the FSMA rules, FSMA programs, and implementation strategies after the rules are final. We encourage stakeholders to first visit FDA's FSMA webpage at www.fda.gov/fsma, which contains detailed information on all aspects of FSMA, including implementation. The webpage includes Frequently Asked Questions (**FAQ**) about FSMA by topic area. Inquiries may be submitted through a web form. The web form can be accessed at www.fda.gov/fsma. Go to "Contact FDA about FSMA" and then Submit Inquiry.

❖ USDA FACILITIES

Please visit USDA at: www.fsis.usda.gov



Poultry growers who have 1000 or fewer birds will need to register with PDA under the Food Establishment Registration program. Producers of non-amenable meats who do not utilize the USDA meat inspection program voluntarily must register with PDA. (See PDA rabbit & poultry requirements on https://www.agriculture.pa.gov/consumer_protection).

REFERENCES

- ❖ To visit the PA Department of Agriculture's Food Manufacturing webpage:
https://www.agriculture.pa.gov/consumer_protection/FoodSafety/manufacturing-packing-holding-distribution/commercial-food-establishments/Pages/default.aspx
- ❖ To visit the webpage of the Pennsylvania Consolidated Statutes:
http://www.legis.state.pa.us/cfdocs/legis/LI/Public/cons_index.cfm
(The Food Safety Act (*known as Act 106*) can be found in Title 3 (*Agriculture*), Chapter 57 (*Food Protection*), Subchapter B (*Food Safety*) §§ 5721 – 5737).
- ❖ To Search the Code of Federal Regulations visit: <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>
(Most FDA Food Regulations can be found in Title 21 and USDA Meat & Poultry regulations can be found in Title 9.)
- ❖ To find the Code of Federal Regulations related to FSMA's new Preventive Controls for Human Food Final Rule (21 CFR 117--cGMPs, Hazards Analysis, and Risk-Based Preventive Controls for Human Food):
<http://www.ecfr.gov/cgi-bin/searchECFR?idno=21&q1=117&rgn1=PARTNBR&op2=and&q2=&rgn2=Part>
- ❖ To find resources and information about the Food Safety Modernization Act (FSMA) of 2011, and how Penn State Extension is responding and assisting industry:
<http://extension.psu.edu/fsma>

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TRAINING OPPORTUNITIES

For food establishments that are subject to the full Preventive Controls requirements, the regulation requires that certain activities must be completed by a Preventive Controls Qualified Individual (PCQI) who has successfully completed training in the development and application of risk-based preventive controls. FSPCA has developed a standardized curriculum recognized by FDA; and successfully completing this course is one way to meet the requirements for a PCQI.

These courses are taught by Lead Instructors trained by the FSPCA, who have been instructed in how to teach the FDA-recognized standardized curriculum.

List of upcoming courses and registration information can be accessed at:

https://fspca.force.com/FSPCA/s/course_registration/Course_Registration_c/00B36000007edjpEAA?language=en_US

For more information about FSPCA Alliance Training opportunities, visit:

<https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>

A copy of the FSPCA PC for Human Food Participant manual can be found at:

https://ifpti.absorbtraining.com/Files/Instructor%20Resource%20Portal/FSPCA%20PC%20Course%20Participant%20Manual_V1.2_2016.02.23.pdf

Other training opportunities can be found on the Penn State Department of Food Science web site:

<https://foodscience.psu.edu/workshops>

GUIDELINES FOR FOOD ESTABLISHMENTS

The following document is not intended to be an all-inclusive list of rules for manufacturer/ processors, distributors and warehouses, but is intended to serve as a guideline and reference material.

The Food Safety Act (3 C.S §§5721 - 5737) sets forth the standard for food establishments manufacturing and processing food in Pennsylvania. It addresses prohibited acts, adulteration and mislabeling of foods among other things. The Department did not promulgate its own regulations, but instead invokes all of the Federal Acts, Code of Regulations (CFR's), relating to food. Therefore, there will be many references to the CFR's throughout this document.

As foods and their processing methods are unique and customized, the code of federal regulations (CFRs) governing manufactured foods can be broad and non-specific; however there are specific food standards for some categories of food (Seafood, Juice, Acidified food, etc.). See links on page 12 of this document.

All PDA registered firms will be expected to comply with the applicable portions of the PCHF regulations regardless of FDA registration status, unless specifically exempted in the rule. During inspection of food establishments, PDA will evaluate the required food safety plans and make sure the plans are being implemented properly.

Food establishments that are subject to PC rule must establish and implement a food safety system that includes:

- Hazard analysis: What are the known or reasonably foreseeable biological, chemical, and physical hazards that occur naturally, are unintentionally introduced, or are intentionally introduced, that could affect the safety of the food.
- Preventive controls: Measures that are required to minimize or prevent the identified hazards, including process controls, allergen controls, sanitation controls, and supply-chain controls.

The written food safety plan must also include procedures for monitoring the implementation of preventive controls, corrective actions procedures, verification procedures, and a record keeping system. Required records shall be made available to regulators for review.

A recall Plan is also required if the hazard analysis reveals that a preventive control is needed.

(See the PDA PCHF fact sheet for more details about the requirements or visit the FDA website at the link provided on page 12).

Food establishments that are exempt or subject to modified requirements of the new requirements for Hazard Analysis and Risk-Based

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Preventive Controls would generally still be subject to modernized current GMP requirements.

Updated Current Good Manufacturing Practices (cGMPs)

The FDA Current Good Manufacturing Practice (GMP) requirements found in 21 CFR 110 has been revised as part of the FSMA new Preventive Controls rule and are now replaced by 21 CFR 117, Subpart B. The new updates include:

- *Clarifications on protections against cross-contact of food by allergens,*
- *Deletion of certain nonbinding provisions (language containing recommendations).*
- *Some previously nonbinding provisions are now modified to be binding provisions. One example is education/training, in which management is now required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.*

<h2 style="margin: 0;">CURRENT GOOD MANUFACTURING PRACTICE UPDATED & CLARIFIED</h2>

The present document will address the general construction, equipment, processes and controls, and sanitation requirements as per the current and updated good manufacturing practices found in 21CFR Part 117 Subpart B, and serving as guidelines to help food establishments be compliant with the regulations in order to ensure that food is manufactured/ processed and or stored under sanitary conditions.

❖ PERSONNEL – CLEANLINESS & HEALTH

Key Points: hand washing, clean outer garments, hair restraints, tobacco/gum use, no jewelry, clothing storage, disease transmissible through food/food products, reporting to management, exclusion and restriction of sick/suspect employees.

Hands shall be thoroughly washed before commencing food plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing their hands. All persons, while engaged in the handling, processing, pasteurization, storage, transportation, or packaging of food and food product, containers, utensils and equipment shall wear clean outer garments. All persons, while engaged in the processing of food and food products, shall wear adequate hair coverings and shall not use tobacco.

Any person who by medical examination, or supervisory observation is shown to have or appears to have an open lesion, cuts, boils, sores, open wounds and like items; illness, or other source of microbial contamination whereby there is a reasonable chance to contaminate food, food products, food product contact surfaces, or food packaging shall be excluded . Personnel are to be trained/ instructed to report such things to supervision.

No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a food plant in any capacity which brings them into direct contact with food or food products or food-contact surfaces.

Regulations on this area can be found in:

21 CFR 117.10(a), 117.10(b)(1)-(9)

❖ PERSONNEL – QUALIFICATIONS & TRAINING

Key Points: qualifications, training, food safety & hygiene, education, experience, competent supervisory personnel, training records.

The management of a food establishment must ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties. These employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food.

Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.

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Responsibility for assuring compliance by all employees with the requirements of this part shall be assigned to competent supervisory personnel who have the education, training and/or experience necessary to supervise the production of clean and safe food.

Records documenting these qualifications and training must be established and maintained.

Regulations on this area can be found in:

21 CFR 117.4(a)-(d).

❖ FLOORS

Key Points: smooth, impervious, trapped drains, no pooled water, sloped to drain as applicable.

The floors of all rooms in which food products are handled, processed, packaged, or stored; or in which food containers, utensils and/or equipment are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped so that there are no pools of standing water after flushing, and the joints between the floor and the walls are impervious, and shall be provided with trapped drains and kept in good repair.

Regulations on this area can be found in:

21 CFR 117.20(b)(4), 117.37(b)(4), 117.37(c)

❖ WALLS AND CEILINGS

Key Points: smooth, washable, impervious, good repair.

Walls and ceilings of rooms in which food or food products are handled, processed, packaged, or stored; or in which food containers, utensils and/or equipment are washed, shall be of a durable, smooth, non-absorbent, washable, light-colored surface and be in good repair.

Regulations on this area can be found in:

21 CFR 117.20(b), 117.20(b)(4)

❖ DOORS AND WINDOWS

Key Points: outer openings protected against entry of flies and rodents, Outer doors self-closing; screen doors open outward.

Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall have solid doors or glazed windows, which shall be closed during dusty weather. All openings to the outer air shall be effectively protected by any method to the extent to prevent the entry of insects, rodents and other pests (e.g. screening, air curtains, self-closing doors, etc.).

Regulations on this area can be found in:

21 CFR 117.20(b), 117.20(b)(7)

❖ LIGHTING AND VENTILATION

Key Points: adequate lighting/ventilation, well ventilated to preclude odors and condensation; filtered air with pressure systems.

All rooms in which food or food products are handled, processed, packaged, or stored; or in which food containers, utensils and/or equipment are washed shall be well lighted and well ventilated. Ample light (natural or artificial) promotes cleanliness. Proper ventilation reduces odors, vapors and prevents condensation upon interior surfaces.

Safety type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be provided or any other means to protect against food contamination from glass breakage (ex. use of plastic shields, plastic sleeves with end caps, shatterproof bulbs, etc.).

Fans and other air blowing equipment must be located in a manner that minimizes potential for contaminating food, food products, food contact surfaces and food packaging.

Regulations on this area can be found in:

21 CFR 117.20(b)(5)-(6)

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❖ SEPARATE ROOMS

Key Points: separate rooms when required, adequate size for intended use, no direct opening into living quarters.

There shall be separate rooms for:

1. The pasteurizing, processing, cooling, reconstitution, condensing, drying and packaging of food and food products.
2. Packaging of dry food and food products.
3. The cleaning of multi-use food containers, bottles, cases and dry food or food product containers.
4. The fabrication of containers and closures for food and food products.
5. Cleaning and sanitizing facilities for over the road tanker trucks in food plants receiving liquid ingredients in bulk that require cleaning upon emptying.

Rooms in which food or food products are handled, processed, stored, condensed, dried and packaged, or in which containers, utensils and/or equipment are washed or stored, shall not open directly into any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

Designated areas or rooms shall be provided for the receiving, handling and storage of returned food and food products.

Regulations on this area can be found in:

21 CFR 117.20(b), 117.20(b)(1)-(2)

❖ TOILET-SEWAGE DISPOSAL FACILITIES

Key Points: no direct openings into process rooms, self-closing doors, clean, ventilated, adequate lighting, properly equipped, sewage / other wastes disposed of in sanitary manner.

Every food plant shall be provided with toilet facilities conforming to the regulations of the appropriate regulatory agency.

Toilet rooms shall not open directly into any room in which food or food products are processed except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner so as not to contaminate food containers, utensils or equipment, or to create a nuisance or a public health hazard.

Regulations on this area can be found in:

21 CFR 117.37(b), (c), (d)

❖ WATER SUPPLY & SAFETY

Key Points: constructed properly, no direct/indirect connections between potable/non potable water, complies with appropriate bacteriological standards.

Water for food plant purposes shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

Running water at a suitable temperature, under pressure as needed, shall be provided in all areas where required.

Private water sources shall comply with the specification outlined in the EPA ground water manual and the Bacteriological Standards outlined herein.

Plumbing shall be of adequate size and design and adequately installed and maintained.

No cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated

Regulations on this area can be found in:

21 CFR 117.37(a), 117.37(b) (1)-(5), 117.80(b)(1), 117.80(c)(16)

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❖ HANDWASHING FACILITIES

Key Points: located, properly equipped, clean, good repair, only hand sinks used for hand washing.

Convenient hand washing facilities shall be provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices. Hand washing facilities shall be kept in a clean condition and in good repair. Hand washing facilities shall be convenient to all toilets and to all rooms in which food plant operations are conducted.

Use of understandable signs directing employees to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated.

Regulations on this area can be found in:

21 CFR 117.37, 117.37(e), 117.10 (b)(3)

❖ PLANT CLEANLINESS

Key Points: no unnecessary equipment, neat, clean, trash properly handled, no evidence of insects/ pests.

All rooms in which food and food products are handled, processed or stored; or in which containers, utensils and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk food or packaged food product storage rooms.

Regulations on this area can be found in:

21 CFR 117.40(a)-(d), 117.35(c)-(d), 117.80(c)(6), 117.37(f), 117.20(b)(6)

❖ CONDITION & CLEANLINESS OF FOOD-CONTACT SURFACES

Key Points: good repair, smooth, non-toxic, approved single service articles and no reuse, effectively cleaned/ sanitized prior to using, proper strength of sanitizer, cleaning done in a manner so it does not become a source of contamination, outer garments and gloves kept in a sanitary condition.

All multi-use containers and equipment that food and food products come into contact with shall be of smooth, impervious, corrosion-resistant, non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All food contact surfaces including outer garments and gloves shall be maintained and kept clean and in sanitary condition.

Articles intended for single-service use shall not be reused.

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of food or food products shall be effectively cleaned and sanitized before each use.

Equipment must be provided to properly clean and sanitize food contact surfaces. This may be accomplished by a 3-compartment sink for washing, rinsing and sanitizing food contact surfaces of equipment. For large pieces of equipment, a clean in place method may be utilized.

Regulations on this area can be found in:

21 CFR 117.10(b)(1) & (5), 117.35(d)(1)-(3), 117.40(a)(1)-(6) & (b), 117.80(c)(1), 117.80(c)(10)

❖ STORAGE OF CLEANED CONTAINERS AND EQUIPMENT

Key Points: stored to assure drainage, protected from contamination.

After cleaning, all multi-use food or food product containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

Containers shall be stored inverted, if practicable, on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, corrosion-resistant, non-toxic materials, or otherwise protected from contamination.

Regulations on this area can be found in:

21 CFR 117.35(f)

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❖ STORAGE OF SINGLE- SERVICE CONTAINERS, UTENSILS

Key Points: received, stored, handled in sanitary manner, single service articles not reused.

Single-service caps, cap stock, parchment paper, containers, gaskets, liners, bags and other single-service articles (plastic forks, single service ladles etc.) for use in contact with food and food products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

Regulations on this area can be found in:

21 CFR 117.35(d)(3)

❖ PROPER LABELING, STORAGE & USE OF TOXIC COMPOUNDS

Key Points: only approved pesticides used, properly identified, properly stored.

Chemicals, poisonous and toxic materials shall be identified, held and stored in a manner to preclude the contamination of food and food products, or ingredients of such food and food products, or the product- contact surfaces of all containers, utensils and equipment. Use of pesticides is permitted only under precautions and restrictions that will protect against contamination of food, food-contact surfaces or food-packaging materials.

Regulations on this area can be found in:

21 CFR 117.35(b)(2), 117.35(c)

❖ PROTECTION FROM CONTAMINATION (ADULTERATION)

Key Points: operations conducted/located to preclude food/food product/food product contact surface contamination, air and steam used to process foods in compliance, protecting food in outdoor fermentation vessels.

Equipment and utensils used in the food plant shall be of adequate design and material as to be easily cleaned and properly maintained to preclude the adulteration of food. Cleaning & sanitizing of equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

The codes do not dictate the exact type of equipment that is needed by a food processor. Whatever the equipment, it must be designed, constructed, and used in a manner that does not allow for the contamination or adulteration of the food.

All operations in the food plant including but not limited to receiving, transporting, preparing, manufacturing, packaging and storing shall be conducted in accordance with adequate sanitation principles.

Regulations on this area can be found in:

21 CFR 117.20(b)(4), 117.35(a), 117.40(a)(1)-(6), 117.80(a)(1)-(6), 117.80(b)(5), 117.80(b)(7), 117.80(c)(5), 117.80(c)(7), 117.80(c)(10), 117.80(c)(12), 117.80(c)(13), 117.93.

❖ TRANSPORTATION, WAREHOUSE & DISTRIBUTION

Key Points: adequate storage, capable of protecting food/food products in transit and during storage, capable of maintaining food temperature as appropriate, clean, no toxics transported.

Adequate and suitable floor space shall be provided for the storage of foods, ingredients and or finished products. Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial (including radiological) contamination as well as against deterioration of the food and the container.

All vehicles used for the transportation of food or food products shall be constructed and operated so that the food or food product is maintained at the appropriate temperature and to protect the food from contamination. Vehicles may not be used to transport or contain any substances that may be toxic or harmful to humans.

Regulations on this area can be found in:

21 CFR 117.93

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❖ SURROUNDINGS

Key Points: neat, clean, no harborage, no pooled water, approved pesticides used properly, rooftops clean.

Food plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance. Waste material shall be stored in suitable covered containers.

No accumulation of trash, garbage or similar waste in areas adjacent to the food plant. This includes properly storing equipment, removing waste and trash, cutting weed/grass/other vegetation in the immediate vicinity of the plant buildings and structures that may constitute harborage areas for pests.

Only insecticides and rodenticides approved for use by the Regulatory Agency and/or registered with EPA shall be used for insect and rodent control.

Areas that may contribute to food contamination through seepage, foot borne filth, etc. shall be drained adequately. Said drainage shall serve to preclude a harborage/ breeding area for pests.

Regulations on this area can be found in:

21 CFR 117.20(a) (1)-(4), 117.35(b) (2)

❖ FOOD PROCESSES & CONTROLS

Key Points: adequate processing, appropriate testing, adequate sanitation, protection of food/ ingredients through all steps of production and manufacturing including storage.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging and storing of food shall be conducted in accordance with adequate sanitation principals and should all be considered when becoming a food processor.

There must be a competent person in charge within the establishment. Production procedures may not contribute to contamination of the food. Chemical, microbial, or extraneous materials must be monitored to assure there is no product contamination or adulteration.

Some foods will require product testing to support specific production and storage needs. Time, temperature, humidity, pH, pressure, flow rate, Aw and other monitoring tests may need to be performed. This testing is product dependant and can be discussed with your Inspector. Potentially hazardous foods must be produced, stored, and transported in a manner to control the growth of microbial contaminants; therefore proper refrigeration/freezer storage is necessary.

Regulations on this area can be found in:

21 CFR 117.80, 117.4

❖ HOLDING & DISTRIBUTION OF FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD

Key Points: properly designed and clean containers, protection against contamination by trash, labeling of containers, identification of containers, sanitary transportation.

Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor must be held under conditions that will protect against contamination, including the following (21 CFR 117.95(a)):

Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food.

Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash.

During holding, human food by-products for use as animal food must be accurately identified.

In addition:

Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed (21 CFR 117.95(b)).

Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food (21 CFR 117.95(c)).

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Regulations on this area can be found in:

21 CFR 117.95(a)-(c)

❖ DEFECT ACTION LEVELS

Key Points: control of unavoidable defect levels, adulteration of mixed foods containing variable defect levels, defect level handbook.

The manufacturer, processor, packer, and holder of food must utilize quality control operations at all times that reduce natural or unavoidable defects to the lowest level currently feasible.

The mixing of a food containing defects at levels that render the food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at <http://www.fda.gov>.

Regulations on this area can be found in:

21 CFR 117.110(a)-(b)