

GUIDELINES FOR FOOD ESTABLISHMENT CONSTRUCTION SANITARY PRACTICES

FOOD MANUFACTURING / PROCESSING / WAREHOUSING / DISTRIBUTION/ WHOLESALE

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 Good Manufacturing Practices CFR's governing processed/manufactured foods can be broad and non-specific; however there are specific food standards for some categories of food (see links at the end of this document)

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. Both parts 110 and 117 will be cross referenced throughout this document. The revised GMPs will continue to support HACCP for Juice and Seafood as well as support the new Food Safety Plan required for other food processors. 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. 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.

The present document will address the general construction, equipment and sanitation requirements as per the current and updated good manufacturing practices found in 21CFR Part 110 and Part 117, subpart B, and serving as guidelines to help food establishments be

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compliant with the regulations in order to ensure that food is manufactured/ processed and or stored under sanitary conditions.

❖ 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 110.20(b)(4), 110.37(b)(4), 110.37(c)

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 110.20(b), 110.20(b)(4)

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

❖ DOORS AND WINDOWS

Key Points: outer openings effectively 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 110.20(b), 110.20(b)(7)

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

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❖ LIGHTING AND VENTILATION

Key Points: adequate lighting/ventilation all rooms, 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 110.20(b)(5)-(6)

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

❖ 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

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Regulations on this area can be found in:

21 CFR 110.20(b), 110.20(b)(1)-(2)
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 110.37(b), (c), (d)
21 CFR 110.37(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 110.37(a), 110.37(b) (1)-(5), 110.80(a)(1), 110.80(b)(16)
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 110.37, 110.37(e) (1)-(6), 110.10 (b)(3)

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 110.40(a)-(d), 110.35(c)-(d), 110.80(b)(6), 110.37(f), 110.20(b)(6)

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

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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 110.10(b)(1) & (5), 110.35(d)(1),(2) & (4), 110.40(a)-(b), 110.80(b)(1), 110.80(b)(10), 110.80(b)(13)(ii)

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 110.35(e)

21 CFR 117.35(f)

❖ 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 110.35(d)(4)

21 CFR 117.35(d)(3)

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❖ **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 110.35\(b\)\(2\), 110.35\(c\)](#)

[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 110.20\(b\)\(4\), 110.35\(a\), 110.40\(a\), 110.80, 110.80\(a\)\(5\), 110.80\(a\)\(7\), 110.80\(b\)\(5\), 110.80\(b\)\(7\), 110.80\(b\)\(10\), 110.80\(b\)\(12\), 110.80\(b\)\(13\), 110.93.](#)

[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.](#)

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❖ PERSONNEL – CLEANLINESS

Key Points: hands washed often as necessary, rewashed as needed, clean outer garments, effective hair restraints, no use of tobacco/gum, remove jewelry, clothing storage.

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.

Personnel responsible for identifying sanitation failures or food contamination have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean safe food

Regulations on this area can be found in:

21 CFR 110.10(b)(1)-(9), 110.10(c)

21 CFR 117.10(b)(1)-(9), 117.4(c).

❖ 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 110.93

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 110.20(a) (1)-(4), 110.35(b) (2)

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

❖ EMPLOYEE & PERSONNEL HEALTH

Key Points: disease transmissible through food/food products, reporting to management, exclusion and restriction of sick/suspect employees, right to decline examination and consequences.

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.

Responsibility for assuring compliance by all employees with the requirements of this part shall be assigned to competent supervisory personnel.

Regulations on this area can be found in:

21 CFR 110.10(a) & (d)

21 CFR 117.10(a), 117.4(c)

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❖ **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 Sanitarian. 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 110.80

[21 CFR 117.80, 117.4](#)

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ADDITIONAL INFORMATION:

❖ **REGISTRATION WITH THE PA DEPARTMENT OF AGRICULTURE**

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 processors ***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 (***HARPC***) 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.

For more information about the FDA’s FSMA Preventive Controls Final Rule, visit:

www.fda.gov/fsma OR

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



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.

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❖ **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.

REFERENCES:

- [Click here to visit the PA Department of Agriculture's Food Manufacturing webpage.](#)
- [Click here to visit the webpage of the Pennsylvania Consolidated Statutes.](#) (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).
- [Click here to Search the Code of Federal Regulations.](#) (Most Food Regulations can be found in Title 21, USDA Meat & Poultry regulations in Title 9.)
- [Click here to view the PA Food Protection Act.](#)
- [Click here to find the Code of Federal Regulations related to FSMA's new Preventive Controls for Human Food Final Rule \(21 CFR 117-- cGMPs, Hazards Analysis, and Risk-Based Preventive Controls for Human Food\).](#)
- [FSMA PC Rule - PDA Fact Sheet \(pdf\)](#)