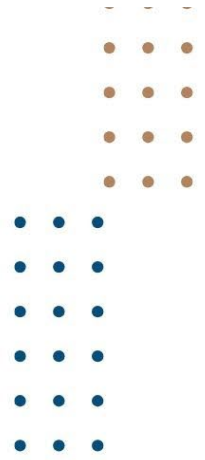


ILLINOIS DEPARTMENT OF PUBLIC HEALTH

# PREPARING FOR WHOLESALE



THE  
MANUFACTURED FOOD  
GUIDE

IDPH Food Protection  
Program



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## Purpose

**This document has been prepared by the Illinois Department of Public Health's (IDPH) Food Protection Program to assist small processors interested in starting a wholesale food business.**

IDPH protects residents and visitors through statewide programs and support of local programs to promote food safety and to reduce the incidence of foodborne illness.

The food industry is responsible for producing safe food. IDPH and local food protection programs are responsible for setting food safety standards, conducting inspections, and monitoring food products. Illinois public health officials monitor the state's food supply at various steps in the food chain to assure food stays safe.

The guidance document is intended to provide a general overview of the sanitary requirements for operating a food processing facility for wholesale based on 21 CFR 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food.

The guide was written for small food processors who may face challenges in transitioning from operating a retail food establishment or cottage food operation into a wholesale food processing business.

**The guide is not all inclusive.** Because food businesses vary in their products, business plans, and processes, examples are only meant to help understand the process. A food safety plan to prevent or minimize the likelihood of foodborne illness or injury should be developed specific to your business and products.

## Contact Us

Feedback on this guide can be emailed to: [DPH.MfgFood@illinois.gov](mailto:DPH.MfgFood@illinois.gov).

Additional IDPH food safety resources can be found at <https://dph.illinois.gov/topics-services/food-safety.html>.

## Food Safety Agencies

**Different agencies regulate different parts of the food supply. It is important to understand what agency regulates your product(s) and what regulations apply.**

### Wholesale

Generally, wholesale refers to the sale of food from one business to another for resale or reservice (e.g., selling food to a grocery store or restaurant). It also may apply to indirectly selling food through another business such as consignment.

#### Illinois Department of Agriculture and U.S. Department of Agriculture

The U. S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) protects the public's health by ensuring meat, poultry, and egg products are safe, wholesome, and properly labeled.

Illinois Department of Agriculture (IDOA) regulates meat, poultry, shell eggs, and products containing a certain amount of meat or poultry (e.g., sausage pizza or chicken egg rolls) in Illinois.

#### U.S. Food and Drug Administration

The U.S. Food and Drug Administration (FDA) protects consumers against impure, unsafe, and fraudulently labeled products. FDA, through its Center for Food Safety and Applied Nutrition (CFSAN), regulates food other than meat, poultry, and egg products regulated by USDA FSIS.

If a business is primarily wholesale or products are sold interstate (over state lines), the FDA also has jurisdiction.

#### Illinois Department of Public Health

IDPH regulates food products (including beverages) other than the meat, poultry, and egg products regulated by USDA or IDOA processed, packaged, labeled, stored, and distributed for wholesale in Illinois.

### Retail

Products sold directly to consumers, including online or at farmers markets, are considered retail sales and are regulated by local health departments.

### Multiple Regulatory Agencies

Your business may be regulated by multiple regulatory agencies based on the products and business plan.

## Rules and Regulations for Wholesale or Manufactured Food

**Understand what regulations apply to your business based on your size and products.**

### Illinois Requirements

Wholesale food operations in Illinois must follow the requirements in the Manufacturing, Processing, Packing or Holding of Food Code (77 Ill. Adm. Code 730), which can be reviewed at [Manufacturing Processing, Packing or Holding of Food Code \(77 Ill. Adm. Code 730\)](#).

To be inspected by IDPH, you must be registered. To register, you must complete and submit the manufactured food application. A floor plan and product labels should be included. After IDPH receives and reviews the application, an IDPH inspector will be in contact to schedule an inspection.

To learn more about this process, visit [IDPH Wholesale Food Operations/Manufactured Food](#).

### Federal Requirements

Federal requirements for wholesale food processing also apply. In Illinois, IDPH has adopted 21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food which can be reviewed at [21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food](#).

### The Food Safety Modernization Act and Registration with FDA

The FDA Food Safety Modernization Act (FSMA) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States to submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.

FSMA also requires food facilities required to register with FDA to renew registration every other year and provides FDA with authority to suspend registration of a food facility in certain circumstances. To learn more about the registration and how to register food facilities, visit [FDA Registration of Food Facilities and Other Submissions](#) or [FDA Online Registration of Food Facilities](#).

Basically, food firms primarily engaged in wholesale must register with FDA and re-register every two years on even numbered years.

### Qualified Facilities and FDA Facility Attestation

A business that meets the definition of a "qualified facility" is subject to modified requirements of the preventive control's rules. Qualified facilities are generally small businesses. Firms that meet the definition of a qualified facility will have less than \$1 million (adjusted for inflation) in annual sales of human food per year during a three-year period (includes subsidiaries and affiliates). The current inflation adjusted cut offs can be viewed at [FDA FSMA Inflation Adjusted Cut Offs](#).

These modified requirements can be met by submitting a form to FDA, attesting to the business's status as a qualified facility and that the facility is implementing preventive controls to address hazards associated with its food or follows non-federal food safety laws and regulations.

Firms that want to attest to FDA must complete Form FDA 3942a and submit it to FDA. More information about qualified facilities and attestation can be found at [FDA Qualified Facility Attestation](#).

## The Basics

**Learn more about the basics needed to operate a safe wholesale food operation.**

The following represents the basic requirements for operating a processing operation, including facilities, construction, transportation, production and process control, sanitation control procedures, labeling and advertising, licensing and permits, training, and inspections.

### Choosing a Facility or Co-Packer

**Understanding options for producing and storing food for wholesale.**

If you plan to produce food yourself, the first thing to consider is choosing a facility where you will produce or store your food.

You may also choose to have your food produced or packaged by a co-packer.

Facilities must be inspected and approved by IDPH. Food ingredients or finished products cannot be produced or stored at a private residence.

#### Commercial Kitchens

Commercial kitchens are commercial-grade facilities owned or rented by food processors to prepare and to store food. Some commercial kitchens are private, which gives you control over the kitchen, your equipment, and the storage. Some commercial kitchens are shared.

#### Shared Kitchens

A shared kitchen is a commercial space approved for food production and storage. This may be a dedicated space with its primary function to serve multiple business owners, a food establishment, or processing plant that rents its commercial kitchen to another business outside its traditional operating hours. If a firm chooses to switch kitchens, the new facility must be inspected and approved by IDPH.

#### Co-Packers

A co-packer or contract packer is a company that undertakes the task of manufacturing and packaging food and other products for its business clients. The co-packer works under contract to produce goods as though they were manufactured by the business client. If a firm chooses to use an in-state co-packer, the facilities must be inspected and approved by IDPH. Out-of-state co-packers must be inspected by the FDA or the state regulatory authority.

Any facility selected should meet the construction requirements in the next section.

## Construction

The facility and surroundings in which food processing and handling operations are conducted must be designed and constructed in a sanitary manner.



Food processing areas must have total separation from other areas in the building.

Doors must be tight fitting and self-closing. Surfaces must be smooth, easily cleanable, and free of defects, cracks, and crevices.

Equipment used in food processing must be of sanitary design, in good repair, easily cleanable, and accessible from all sides to facilitate proper cleaning and sanitizing.

The term “adequate” used in the following list means what is needed to accomplish the intended purpose in keeping with good public health practice.

1. **Proper Sewage Disposal:** Water-carried sewage must be disposed of by means of a public or private sewage disposal system constructed and operated in conformance with applicable state and local laws, ordinances, and regulations.
2. **Safe Water Supply:** The water supply must be adequate, safe, sanitary quality, and from an approved public or private water supply system constructed, protected, operated, and maintained in accordance with applicable state and local laws, ordinances, and regulations.
3. **Safe Plumbing System:** Plumbing must comply with the Illinois Plumbing Code (77 Ill. Adm. Code 890) and Illinois Plumbing License Law (225 ILCS 320).
4. **Proper Ware Washing:** For manual cleaning and sanitizing, normally a three-compartment sink, constructed of a durable, non-corrosive, non-abrasive material (such as stainless steel), must be present. Each compartment must be large enough to permit the complete immersion of equipment and utensils and be supplied by hot and cold running water.
5. **Sanitizing:** An approved chemical sanitizer, such as chlorine or quaternary ammonia, and concentration test kits must be available. If hot water is used for sanitizing, an integral heating device or fixture must be installed in or under the sanitizing compartment of the sink and capable of maintaining the water at a temperature of at least 170°F. Records of sanitizer strength or concentration shall be maintained.
6. **Handwashing:** A hand washing sink must be provided in the food processing and packaging area. Provide hand detergent, sanitary towels, and hot and cold running water through a combination faucet or temperature by means of a mixing valve at each hand washing station. A sign must be posted reminding workers to wash their hands prior to beginning work, after returning from the toilet, or following a break or change in food handling operations.
7. **Lighting:** Adequate lighting must be provided in all areas of the facility.
8. **Protective Shielding:** Protective shielding over light fixtures must be provided in food processing, packaging, and storage areas as well as equipment and utensil storage and washing areas.
9. **Floors:** Floors and floor coverings must be in good repair and constructed of smooth, durable, non-absorbent, and easily cleanable materials.
10. **Walls:** The walls, wall coverings, and ceilings must be in good repair and constructed of a light-colored, smooth, durable, non-absorbent, and easily cleanable material with a minimum of exposed pipes, electrical conduits, and wires outside of the walls.
11. **Ventilation:** Adequate ventilation must be provided to minimize odors and noxious fumes. Mechanically vent the toilet rooms to the outside air.

12. **Outer Openings (Keep Pests Out):** Effectively screen outer openings and provide a self-closing device on the entrance/exit doors to minimize pests.
13. **Toilet Rooms:** Each toilet room must be equipped with self-closing doors and must not open directly into the preparation or food storage rooms/areas, except where alternate means have been taken to prevent such contamination, such as double doors, positive air-flow systems, etc.
14. **Garbage:** Garbage and rubbish containers must be provided that are durable, non-absorbent, and easily cleanable. Containers located/stored outside must also be rodent and insect proof and provided with tight-fitting lids or covers.
15. **Food Preparation/Contact Surfaces:** Food preparation surfaces, counters, and tables must be smooth, durable, non-absorbent, and easily cleanable. Examples include Formica counters with rolled front-edge type, hard maple, or stainless steel.
16. **Storage:** Pallets or storage shelves used for storing raw materials and finished products should be constructed of smooth, non-absorbent, and easily cleanable materials.
17. **Thermometers:** Provide a thermometer in the refrigerator and freezer compartments that will measure the temperature in the warmest part of the unit (near the door and near the top).
18. **Processing Area/Storage Area Separation:** No direct openings from a shipping/receiving dock into storage and processing areas (must have tight fitting doors to prevent potential contamination).
19. **Doors:** Self-closing devices on exterior doors, restroom doors, and other areas as necessary to prevent potential contamination of ingredients, processing areas, storage areas, etc. Doors must be tight fitting.

## Transportation

Safe food transportation is vital to prevent practices that create food safety risks.



Vehicles must be clean and free of pests to ensure safe transportation of food items.

Containers used in transportation must be clean and in good repair. Product transport containers must be equipped with tight-fitting or overlapping lids or doors to protect food from contamination.

Provide product transport containers of such materials and construction to be smooth, easily cleanable, and non-absorbent. Seams and welds must be sealed, smooth, and of non-toxic solder or sealing compounds.

If cold transport is needed, provide a thermometer in the compartment that will measure the temperature in the warmest part of the unit (near the door and near the top). This thermometer should be numerically sealed and accurate to plus or minus 3°F.



## Production and Process Control

**Process controls are important to ensure product integrity throughout processing.**



Process controls describe the processes, procedures, and practices that help monitor and ensure food quality and safety.

Each step of the process must be conducted in such a manner as to ensure appropriate controls have been implemented. These process controls are often validated by a **process authority**. A process authority is an individual who has expert knowledge in the processing of acidified and low acid foods. Process authorities are discussed more in specialized processing.

Deviations from the process must be recorded and properly investigated to determine the cause. Corrective actions must be taken any time a process deviation occurs.

During inspections, IDPH will review production and process controls to ensure critical control points in the manufacturing process are consistently met and adequate science-based barriers exist to prevent pathogen growth and toxin formation.

Examples include:

- Ingredient receiving and inspection procedures.
- Process validation, including microbial challenge studies, if applicable.
- Access to and use of a process authority, if applicable.
- Process monitoring and quality controls, such as those required for implementing HACCP.

### Processing Activities Reviewed During Inspection

Assembling	Distilling	Infusing
Baking	Drying	Mixing
Brewing	Extracting	Packaging or repackaging
Canning	Fermenting	Pickling
Coating	Freezing	Smoking
Cooking	Grinding	Stuffing
Cutting	Heating or reheating	Any other treatment or food preservation process

During an inspection, inspectors may also review:

- Appropriate security measures.
- Effective use of refrigeration, pH-adjustment, water activity reduction, food additives used, commercial sterilization, modified atmosphere packaging, packaging integrity testing, and expiration date validation.
- Allergen control procedures to ensure that unintentional allergen cross-contact of a food allergen into a food does not occur.
- Environmental monitoring records for ready-to-eat foods.

## Sanitation Controls

**Proper cleaning and sanitizing are critical aspects of food safety, as safe food cannot be produced in the absence of proper sanitation procedures.**



Sanitation includes the methods, procedures, and chemicals used to clean food processing equipment, utensils, and food contact surfaces. Good worker hygiene is also an essential aspect of food safety.

During inspections, sanitation control procedures are reviewed to ensure food processing and storage is completed without cross-contamination, on clean and sanitized food contact surfaces, following hygienic practices, and utilizing potable water, while excluding pests and other contaminants.

Examples include:

- Employees should receive training in personal hygiene, good manufacturing practices (GMPs), and cleaning and sanitation procedures.
  - Employees shall be monitored for any health conditions that could compromise food safety.
- Safety of water as described in the construction section.
- Condition and cleanliness of food contact surfaces.
- Prevention of cross contamination and cross contact.
- Maintenance of hand washing, hand sanitizing, and toilet facilities.
- Protection of food from adulterants.
- Proper labeling, storage, and use of toxic compounds.
- Sanitizing procedures, including procedures to ensure the segregation and proper use of non-food chemicals within a facility.
  - Chemicals that must be segregated include cleaning chemicals, fumigants, and pesticides or baits used in or around the facility.
  - Containers must be properly labeled to identify contents.
- Equipment and building maintenance, including:
  - The facility should be located, constructed, and maintained according to sanitary design principles.
  - Equipment should be constructed and installed according to sanitary design principles.
  - There should be linear product flow and traffic control to minimize cross contamination from raw to processed materials.
  - The facility should establish a preventative maintenance program for equipment. The program should include maintenance procedures recommended by equipment manufacturers as well as procedures to check for worn parts.
- Pest control program, including:
  - Procedures for the cleaning and sanitation of the facility and equipment.
  - A master sanitation schedule that includes an effective pest control program should be in place.
  - Pest control records.
- Material handling and storage procedures, including:

- Raw materials and products should be received, stored, and shipped under sanitary conditions and proper environmental conditions (e.g., temperature and humidity) to ensure they are and remain safe and wholesome.
- There should be written specifications for ingredients, products, processes, and packaging materials.

## Documentation and Records

**Written procedures, policies, and records are important ways to demonstrate that work practices and processes are safe.**



These documents and records are how a firm demonstrates compliance with regulations. Records must be maintained for a minimum of two years and must be available for review within 24 hours of a regulatory request.

- **Food Safety Plan (FSP):** An FSP consists of the primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or to minimize the likelihood of foodborne illness or injury. The FSP can be formatted any way the firm wants. More information about FSPs can be found at [FDA Food Safety Plan Builder](#).
- **Hazard Analysis:** A required element of an FSP to identify whether there are hazards requiring a preventive control. The analysis must be written, regardless of whether any hazards requiring a preventive control are identified. Some facilities may not identify any hazards requiring a preventive control.
- **Allergen Control Plan:** A required element of an FSP for separation of unique (different) allergens from ingredient storage to process, to packaging, to labeling, and to final product storage.
- **Recall Plan:** A required FSP element for any product where a hazard requiring a preventive control has been identified. The recall plan must be in writing and detail the exact personnel and procedures needed to recall food products.
- **Employee Training Program and Records:** Firms must have a written employee training program and written employee training records. Employees must receive training in food safety and food hygiene as related to the job tasks they perform.
- **Consumer Complaints:** A log of each complaint must be maintained. Who, what, where, when, why, and how must be included, plus a description of the business' follow-up and, if necessary, a root cause analysis must be performed.
- **Production Records:** A firm must keep food safety related records for items produced each day. These may include pH testing records, cooking temperature logs, cooling temperature logs, and batching logs if using preservatives/ingredients for which formulation must be controlled.

- **Refrigeration/Freezer Records:** A firm must keep monitoring logs for refrigeration and freezers if used to ensure safety of ingredients or finished products.
- **Calibration Records:** A firm must keep records for calibration of equipment used to verify the safety of products. This may include thermometer calibration checks, pH meter control logs, water activity logs, etc.
- **Sanitation Records:** Sanitation records must be maintained and available for review if sanitation is used as a preventive control.

## Labeling

**Food labeling is a vital way to communicate to the consumer basic information so that the consumer can make educated choices on what food to purchase and to consume.**

It is also a legal requirement to produce food in the United States. Some individuals have very acute reactions to allergens, such as peanuts.

Mislabeled food items can be embargoed until corrections are made to the label. The number one source of product recalls in the United States is undeclared allergens.

More information about FDA labeling requirements can be found at [FDA Food Labeling Guide](#).

Nutrition labeling information can be found at [FDA Food Labeling & Nutrition](#).

Basic required elements of food labeling. **Required information must be in English.**

1. **Statement of Identity:** Identifies to the consumer what type of food product it is. A generic name for a product, for example: Chocolate Chip Cookie.
2. **Net Weight:** Should be listed on the same panel as the Statement of Identity. Net weight shall be in metric and in U.S. Customary System.
3. **Ingredient List:** Ingredients must be listed on the product label and in order of predominance (from largest to smallest).
4. **Allergen Labeling:** Any of the nine major allergens must be declared on the product label in a contains statement that is separate from the ingredient list.
5. **Name and Address:** Name and address of the manufacturer, packer, or distributor.
6. **Nutrition Labeling:** A nutrition facts label must be placed with the ingredient list and name and address of the manufacturer, packer, or distributor. Small businesses may be exempt from nutrition labeling requirements.
7. **Lot Code:** The firm must have some way to track batches of product. The code can be any method the firm chooses if they keep track of batch records. Ingredient lot codes must be tracked in case product ingredients are recalled.

## Nutrition Labeling — Exemptions

In reference to 21 CFR, Part 101.9 (j), a firm with fewer than 100 full-time employees and less than 100,000 units sold in the previous year is exempt from nutritional labeling ***provided no nutritional claims are made.***

An establishment that wholesales product must submit annual notification to FDA to maintain existing exemption. NOTE: A firm with less than 10 employees and less than 10,000 units sold does not have to apply to the FDA for an exemption.

## Employee Training

**A firm must demonstrate awareness of the food safety hazards for products produced by the business and how such hazards have been effectively controlled.**



Food handler certificates and certified food protection manager courses include some of the topics in food hygiene and employee health/hygiene that must be included in annual GMP training but are not necessarily adequate to ensure that a business is operating in compliance with 21 CFR 117 or other applicable codes.

### Key Definitions

**Preventive Controls Qualified Individual (PCQI):** A qualified individual that has education, training, or experience in preventive controls. A PCQI is required to prepare and to update the Food Safety Plan.

**Qualified Individual:** An employee that has received the required training in food safety and hygiene that is applicable to their job.

If management is unable to demonstrate adequate knowledge and compliance with 21 CFR 117, then a preventive control qualified individual may be hired to write standard operating procedures which must be followed -or- at least one person involved in the business must take a Preventive Control for Human Food course and ensure compliance with the applicable parts of 21 CFR 117.

Management and employees must receive annual training on the required GMP topics.

Records of each employee's training must be documented in a training log and made available for regulatory review within 24 hours of such a request. Firms conducting specialized processing will be required to have additional training.

## Specialized Processing

**Specialized processing refers to specific types of food products that include Seafood HACCP, Juice HACCP, Acidified, Low Acid Canned Food (LACF), Shellfish, and Grade A Dairy.**

FDA has specific regulations that pertain to these types of processing. These regulations require additional specialized training and record requirements.

- **Seafood Hazard Analysis Critical Control Points (HACCP)** is a systematic approach to identify and to control biological, physical, and chemical hazards related to the receiving, storage, handling,

production, and distribution of fish and fishery products that can cause these products to be unsafe. Seafood is covered in 21 CFR Part 123. The firm is required to have a written Seafood HACCP plan.

- **Juice Hazard Analysis Critical Control Points (HACCP)** is a systematic approach to identify and to control biological, physical, and chemical hazards related to the production of juice sold as such or used as an ingredient in a beverage that can cause a food product to be unsafe. Juice is covered in CFR Part 120. The firm is required to have a written Juice HACCP plan.
- **Acidified Food** is a low-acid food to which acid(s) or acid food(s) are added and which has a finished equilibrium pH of 4.6 or below and a water activity (aw) greater than 0.85. Acidified foods are covered in 21 CFR Part 114. Firms must use a validated process by a process authority to be in conformance with this regulation. A list of process authorities can be found at [AFDO Food Processing Authorities Directory](#). Acidified firms must register their process location and processing procedures with FDA.
- **Low Acid Canned Food (LACF)** includes shelf-stable canned soups, canned meats, and canned vegetables. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classified as low-acid food. LACF regulations are defined in 21 CFR Part 113. Firms must use a validated process by a process authority to be in conformance with this regulation. LACF firms must register their process location and processing procedures with FDA. Canned meats may also be regulated by the Illinois Department of Agriculture (IDOA) and/or the U. S. Department of Agriculture (USDA).
- **FDA National Shellfish Sanitation Program (NSSP)**. FDA and other federal agencies, including state regulatory agencies, tribes, academia, and the shellfish industry, work together in a cooperative program to keep molluscan shellfish safe for consumption by adhering to strict controls on their growing, harvesting, processing, packaging, and transport. Firms approved to distribute shellfish are listed on the Interstate Shellfish Shippers List. The NSSP Guide for the Control of Molluscan Shellfish 2019 Revision is the most current shellfish guidance.
- **Grade A Dairy and Manufactured Dairy** processing plants must be licensed by the IDPH Dairy Program. Dairy processing plants have different specific regulatory requirements separate from manufactured food requirements. For dairy questions, contact the dairy program at [DPH.Dairy@illinois.gov](mailto:DPH.Dairy@illinois.gov).



**ILLINOIS DEPARTMENT OF PUBLIC HEALTH  
FOOD PROTECTION PROGRAM**

**SELF-INSPECTION CHECKLIST**

**FOR WHOLESALE FOOD PROCESSORS**

The following self-checklist has been developed by the IDPH Food Protection Program as guidance. This guidance is not all-inclusive and may not cover all standards or regulations that may apply to your business.

The items listed are major areas IDPH reviews when performing inspections of wholesale food operations. The following requirements are outlined in IDPH's wholesale food business guidance and regulations and are provided as minimum standards of health and safety for the preparation of wholesale foods.

Where "no" is selected, consider further reviewing the requirement and your processes and develop and implement appropriate corrective actions. If "no" is selected because it is not applicable (e.g., no specialized processing), make a note in the section.

Additional information about wholesale/manufactured food can be found on the IDPH website: <https://dph.illinois.gov/topics-services/food-safety/manufactured-food.html>.

SELF-INSPECTION CHECKLIST  
FOR WHOLESALE FOOD PROCESSORS

**EMPLOYEE TRAINING AND HYGIENE**

1. Employees have been adequately trained in food safety and food hygiene in such a way as to make them qualified to perform their work duties. Training records are maintained for at least two years. Training records are available for review.  
Yes No
2. Employees affected with any communicable disease are not allowed to work on site until they are free of disease. No employee with open lesions, wounds, cuts, sores, or boils is allowed to work in any area where food is handled, processed, packaged, or stored.  
Yes No
3. Employees shall wear hair coverings during food-related tasks. No tobacco products, food, or beverages shall be allowed to be consumed or stored in the food processing area.  
Yes No
4. Employees involved with the preparation and packaging of food products will clean their hands and exposed portions of their arms before starting food processing and after any activity that renders their hands unsanitary. Proper employee handwashing is carried out often—after touching bare body parts, such as the face or hair; after using the toilet; after touching animals; after coughing or sneezing; after eating, drinking, or using tobacco products; after handling soiled equipment; when changing tasks; before donning gloves; and any other activity that may contaminate the hands.  
Yes No

**PLANTS AND GROUNDS**

5. Food facility surroundings shall be neat, clean with no harborages, no pooled water, approved pesticides used properly, and rooftops clean. This requirement would include removing garbage, trash, and other waste from the grounds. In addition, vegetation must be cut regularly in the surrounding area to prevent harborage areas for pests.  
Yes No
6. Rooms need to be adequate for size and intended use. Food processing, packaging, and storing areas shall be separated from living quarters and not open directly into a room used for domestic purposes or for non-food related purposes. Rooms to be separated by tight fitting doors.  
Yes No
7. The floors of rooms in which food products are handled, processed, packaged, or stored shall be constructed of non-absorbent and easily cleanable materials that are smooth and in good repair. Floors should be sloped to prevent standing water.  
Yes No



SELF-INSPECTION CHECKLIST  
FOR WHOLESALE FOOD PROCESSORS

**PLANTS AND GROUNDS continued**

8. Doors and windows shall be tightfitting and prevent entry of pests. Doors shall be self-closing. Windows or doors that are open shall be screened to prevent entry of insects, rodents, and birds.  
 Yes  No
9. Lighting shall be adequate in hand-washing areas, dressing and locker rooms, toilet rooms, and areas where food is examined, manufactured, processed, packed, or held. Provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.  
 Yes  No
10. Ventilation shall be adequate to minimize dust, odors, and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food. Locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.  
 Yes  No

**SANITARY OPERATIONS**

11. Buildings, fixtures, and other physical facilities of the food processing/kitchen must be maintained in a clean and sanitary condition and be in good repair. All operations in the food processing plant/kitchen shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials and allergen cross-contact.  
 Yes  No
12. Chemicals, including pesticides, should be used according to the label instructions, and stored in a manner to prevent contamination of food contact surfaces, ingredients and finished products, single use articles, and packaging materials. Containers must be labeled to identify contents.  
 Yes  No
13. Pests must not be allowed into any area of a food processing facility. Effective measures must be taken to exclude pests from any manufacturing, processing, packing, and holding areas and to protect the premises from the contamination of food by pests. The use of pesticides in the facility must be done using precautions and restrictions that protect food, food-contact surfaces, and food-packaging materials from contamination.  
 Yes  No
14. Single service articles shall not be reused. Single service articles shall be received, stored, and handled in a sanitary manner.  
 Yes  No

SELF-INSPECTION CHECKLIST  
FOR WHOLESALE FOOD PROCESSORS

**SANITARY OPERATIONS continued**

15. Food contact surfaces, equipment, and utensils used for the preparation, packaging, or handling of food products shall be cleaned and sanitized before each use or between product runs of products with different allergen profiles. Non-food contact surfaces or equipment used in the operation of the facility must be cleaned in a manner and as necessary to protect against allergen cross-contact and contamination of food, food contact surfaces, or food-packaging materials.

Yes  No

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

Yes  No

**SANITARY FACILITIES AND CONTROLS**

17. Potable water is used for hand washing, ware-washing, and as an ingredient. Water shall be from a supply properly located, protected, operated, and easily accessible. Water shall be under pressure, adequate, safe, and of sanitary quality. Private water sources must undergo additional testing to prove that the water supply is safe for food production. Plumbing shall be installed and maintained in a manner that meets the state plumbing code. No cross-connections between safe and unsafe water supplies shall be allowed.

Yes  No

18. Food processing facilities will be equipped with toilet facilities. Toilet rooms shall not open directly into food processing areas. Toilet rooms shall have self-closing doors, adequate ventilation and lighting, properly equipped sewage disposal, and be clean and in good repair.

Yes  No

19. A separate hand sink is required in the food processing area for handwashing. The facility must have enough liquid soap, paper towels, and adequate hot water for handwashing and always available at the handwashing sink(s).

Yes  No

20. Any trash or garbage must be conveyed, stored, and disposed of to minimize odors and the potential for the waste becoming an attractant and harborage or breeding place for pests.

Yes  No

SELF-INSPECTION CHECKLIST  
FOR WHOLESALE FOOD PROCESSORS

**EQUIPMENT AND UTENSILS**

21. Food processing equipment and utensils in the food processing area shall be of sanitary design and properly maintained to prevent adulteration of food. All parts of the equipment shall be accessible for inspection. Equipment shall be easily cleanable and able to be sanitized properly. Seams on food-contact surfaces must be smooth or maintained to minimize the opportunity for contamination or allergen cross-contact.  
Yes No
22. A three-compartment sink is required. The three-compartment sink must be separate from the handwashing sink. The sink must meet the state plumbing code and be large enough to wash, rinse, and sanitize utensils. Test strips are required to test that the sanitizer concentration is always adequate. Maintain records of sanitizer testing results to document adequate sanitizer strength.  
Yes No
23. A calibrated thermometer is required for walk-in coolers and freezers along with a temperature log or alarm. Calibration records must be available for review. Walk-in coolers and freezers must be clean, in good repair, and able to maintain appropriate temperatures. Mechanical equipment shall be maintained in clean condition and in good working order. A preventive maintenance schedule for mechanical equipment is advised.  
Yes No
24. Instruments and controls used for measuring time, temperature, humidity, pH, pressure, flow rate, water activity, and other monitoring tests must be accurate and precise. Instruments and controls must be adequately calibrated, maintained, and sufficient in number for designated uses. Production records and calibration records shall be available for review.  
Yes No
25. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.  
Yes No

**PROCESSES AND CONTROLS**

26. Ingredients used in food production must be food grade.  
Yes No
27. Adequate processing, appropriate testing, adequate sanitation, and protection of food/ingredients through all steps of production and manufacturing, including storage, must be maintained.  
Yes No

SELF-INSPECTION CHECKLIST  
FOR WHOLESALE FOOD PROCESSORS

**PROCESS AND CONTROLS continued**

28. Allergens must be segregated to prevent allergen cross-contact during all steps of processing from receiving to storage and distribution. Processing equipment used must be properly cleaned and sanitized between production of products that contain different allergens to prevent cross-contact.  
Yes No
29. Firms that have specialized processing must meet requirements that are specific to the type of processing done in the plant.  
Yes No
30. Firms that produce ready-to-eat food where recontamination with an environmental pathogen is a hazard that requires a preventive control must have an environmental monitoring program.  
Yes No

**TRANSPORTATION, WAREHOUSE, AND DISTRIBUTION**

31. Adequate and suitable floor space shall be provided for storage of food ingredients, packaging, labels, and the finished products. Food ingredients and allergens shall be stored to protect against allergen cross-contact. Do not store ingredients, packaging, or the finished product under sewer pipes, other utilities ,or directly on the floor. Do not store food directly next to walls.  
Yes No
32. When transporting food products, make sure the vehicle or trailer is clean and food products are transported in containers that keep dirt, dust, bugs, or other contaminants away from the food products. Containers must be properly cleaned and sanitized and stored in a clean space when not in use. A thermometer and temperature log are required when transporting items that are required to be maintained under refrigeration.  
Yes No

**FOOD PACKAGING AND LABELING**

33. Food packaging must be made from food grade materials and properly stored.  
Yes No
34. Labeling must meet Food and Drug Administration (FDA) requirements. Labeling needs to include a statement of identification, net weight, ingredient list, allergen statement, name and address of firm, nutrition labeling, if applicable, and some type of batch or lot code.  
Yes No

**RECORDS AND DOCUMENTATION**

35. Firms subject to 21 CFR Part 117 are required to maintain employee training records .  
Yes No

SELF-INSPECTION CHECKLIST  
FOR WHOLESALE FOOD PROCESSORS

**RECORDS AND DOCUMENTATION continued**

36. Firms subject to 21 CFR Part 117 are required to maintain calibration records for equipment used to verify the safety of your products.  
Yes No
37. Firms subject to 21 CFR Part 117 are required to maintain a log for consumer complaints, the firm response, and any corrective actions.  
Yes No
38. Firms subject to 21 CFR Part 117 are required to have a written Food Safety Plan. The Food Safety Plan must include a written hazard analysis, allergen control plan, and recall plan. Specialized processing, such as Juice HACCP or Seafood HACCP, are required to have a written HACCP plan.  
Yes No
39. Firms subject to 21 CFR Part 117 are required to maintain records for any preventive control that is identified in the hazard analysis. These records include production records, sanitation records, and environmental monitoring records.  
Yes No