

**LOUISIANA DEPARTMENT OF HEALTH  
OFFICE OF PUBLIC HEALTH  
FOOD & DRUG/MILK & DAIRY UNIT**

**BASIC REQUIREMENTS FOR PROSPECTIVE FOOD MANUFACTURERS, PROCESSORS,  
PACKERS AND REPACKERS**

(Revised 7/12/17)

The information in this document has been prepared to provide basic information for those persons desiring to manufacture, process, pack and hold food products within Louisiana primarily for wholesale and institutional distribution. The requirements specified herein are minimal and are not intended to replace or supersede applicable regulations. Complete rules and regulations pertaining to manufacture, processing, packing, holding of food products are found in Title 51, Part VI of the Louisiana Administrative Code. Please refer to Section O of this document for information on obtaining copies of the Title 51, L.A.C.

- A. Permits:** No person shall operate a facility engaged in the manufacturing, processing, packing or holding of food products within Louisiana without a valid permit to operate issued by the State Health Officer through the Food & Drug Unit of the Office of Public Health. Permits to Operate expire annually on June 30. The permit fee for food manufacturers, processors, packers, and re-packers will be calculated on a sliding scale based on the gross annual sales of the establishment. Forms for reporting the gross annual sales can be obtained from the program coordinator assigned to your region/district. Permit fees are assessed as follows:

<i><b>ESTABLISHMENT TYPE</b></i>	<i><b>FEE AMOUNT</b></i>
Food Product Manufacturers, Processors and Re-packers	<i>Based on gross annual sales</i> Less than \$500,000            \$175 \$500,001 - \$1,000,000       \$475 \$1,000,001 - \$2,500,000     \$775 \$2,500,000 - \$5,000,000     \$1,075 Greater than \$5,000,000      \$1,375
Food Storage Facilities and Warehouses	\$300.00 Flat Fee
Seasonal Honey Processors/Packers	\$45.00 for three consecutive months; \$15.00 for each additional month
Special Event/Temporary Food Manufacturers, Processors or Packers	\$45.00 per event

- 1. Plans and Specifications.** Prior to issuance of a permit and before beginning construction, plans and specifications for the proposed project shall be submitted to the Food & Drug Unit for compliance review. Plans should be drawn to scale and should include the following

minimum information: 1) a plot or site plan page, 2) a top elevation page showing layout and dimensions of all rooms, location of all doors and window, and position of processing equipment, 3) a schedule of surface materials including specifications on surfaces and coatings, 4) a plumbing riser diagram showing potable water supply lines, sewage and drain lines including floor drains, placement of sinks, location of hand lavatories and restroom fixtures, 5) an electrical diagram showing location, numbers of lighting fixtures, and shielding (where applicable).

In addition, the local Parish Health Unit should be contacted regarding the approval status of the source of potable water and the method of wastewater disposal. For new construction, if a sewer is not available, it may be required to apply for and install an onsite wastewater disposal system. A link to the locations of Parish Health Units may be found here: <http://www.ldh.la.gov/index.cfm/page/394>.

**2. Facility Inspection.** After plans and specifications have been reviewed and approved and construction of the facility has been completed or is near completion, an inspection of the facility shall be made to verify compliance and to accept the necessary applications for permit registration or licensure and the required permit fees.

**B. PRODUCT / LABEL REGISTRATION:** As required by the State Food, Drug and Cosmetic Law, each manufacturer, processor, packer or private-label distributor of processed foods in package form must register each separate and distinct product annually. Firms shall submit to the Food & Drug Unit a complete Application for Registration Form [FD-9(N)] together with copies of labels for each item and applicable registration fees. The registration fee is currently \$27.00 per separate and distinct product up to a maximum charge of \$270.00 per year. **Please note that more than 10 separate product types may be registered by a given corporation—and copies of all labels must be sent to OPH—but only the first 10 types are charged a registration fee.** Note that LDH no longer registers alcoholic beverage products and it does not regulate dietary supplements.

**C. LABELS / LABELING:** All processed food products sold within the state must be labeled in accordance with applicable labeling rules and regulations. The submission of printer's proofs of proposed labels to the Food & Drug Unit for review and approval prior to printing final labels is highly recommended. (Failure to do so may result in reordering labels which are determined to be out of compliance with state and federal regulations.) All food labels must bear the following mandatory information:

- 1. Statement of Identity.** The statement of identity of the food shall appear on the principal display panel of the package or container and shall be in terms of the common or usual name of the food or, if there are established standards for the food, the standardized name.
- 2. List of Ingredients.** If the food is composed of two or more ingredients, the package or container shall bear a listing of each ingredient in descending order of predominance by weight. The ingredient declaration may appear on either the principal display panel or the information panel. Federal labeling regulations now require full disclosure of all ingredients including an ingredient which itself contains two or more ingredients. Ingredients shall be listed by the common or usual name (no brand names). Chemical preservatives shall be declared by their common or usual name and include a separate statement of the functional use of the chemical preservative. Example: "sodium benzoate as a preservative".
- 3. Name and Place of Business of Manufacturer, Packer or Distributor.** The label of a food in package form must specify conspicuously the name and place of business of the manufacturer,

processor, packer, or distributor. This information may appear on either the principal display panel or the information panel. In cases where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with the food; such as “Manufactured for \_\_\_\_\_”, “Distributed by \_\_\_\_\_”, “Packed for \_\_\_\_\_” or any other wording that expresses the facts; however, the name of the actual manufacturer or packer shall be furnished to the department upon request.

- 4. Net Quantity of Contents.** Each unit package of a processed food shall bear a statement of the net quantity of contents. Net quantity of contents declaration criteria are as follows:

Placement of Declaration	Lower 30% of Principal Display Panel in lines generally parallel to the base of the package or container.
Declaration terms	Weight, measure, or numerical count or a combination of numerical count and weight or measure.
If food is a liquid	Use units of measure: fluid ounces, pints, quarts, gallons. Must include Metric equivalent: Net 12 fl oz (355 mL). Net Contents 1 gal (3.79 L), Net 500 mL (1 pt. 0.9 fl oz). Periods, commas after words are optional.
If food is a fresh fruit or vegetable	Use units of dry measure: pint (dry), quart (dry), peck, bushel.
Language	Mandatory information must appear in the English language.

- 5. Print / Type Size Specifications.** The net quantity of contents declaration must be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following specifications:

<b><i>Area of Principal Display Panel</i></b>	<b><i>Minimum Type Size</i></b>
5 in <sup>2</sup> or less	Not less than 1/16 inch in height
> 5 in <sup>2</sup> but not more than 25 in <sup>2</sup>	Not less than 1/8 inch in height
> 25 in <sup>2</sup> but not more than 100 in <sup>2</sup>	Not less than 3/16 inch in height
> 100 in <sup>2</sup> but not more than 400 in <sup>2</sup>	Not less than ¼ inch in height
More than 100 in <sup>2</sup>	Not less than one-half inch in height
If declaration is blown, embossed, or molded onto glass or plastic surface.	Increase type sizes specified above by 1/16 of an inch.

- 6. Nutrition Facts Labeling.** Nutrition information relating to food must be provided for all products intended for human consumption and offered for sale unless a specific exemption is provided for. If an operation employs fewer than 10 full-time employees and sells fewer than 10,000 units of a product per annum, it is granted an automatic exemption. If an operation employs fewer than 100 full-time employees and sells fewer than 100,000 units of a product per annum, it will be granted an exemption *provided that a request is filed annually with FDA*. A nutrient content claim, health claim or any other nutrition information on the label or in labeling or advertising in any context, and in any form of expression, implicit, as well as explicit, shall

negate any exemption and subject a food to providing nutrition information in accordance with applicable regulations. Please see <https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/default.htm> for further details.

- 7. Allergen Labeling.** If your product contains one or more major food allergens, the items must be listed in one of two ways to comply with federal labelling regulations: 1) by usual or common name in the ingredient statement or 2) in a separate “contains” statement which lists the actual allergen present in the product (not the group to which it belongs). The eight major food allergens are milk, egg, soy, wheat, fish, crustacean shellfish, tree nuts, and peanuts. For more information on allergen labelling, please see this site: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm>.

**D. BUILDINGS.** All buildings used for manufacturing, processing, packing or re-packing food shall

1. Be well-lit with an intensity of not less than forty (40) foot-candles on all work surfaces and well-ventilated through means of forced-air ventilation to remove excessive heat, steam, moisture, vapors, smoke and dusts.
2. Maintain all floors, walls, ceilings, work tables, food contact surfaces, and other fixtures in such a condition that they may be readily made clean and sanitary.
3. Floor drains adequate in size (4” recommended—follow International Plumbing Code requirements) and number properly trapped and vented shall be provided in those areas of food manufacturing and processing plants where water overflow is unavoidable or stationary equipment must be cleaned and sanitized in place.

**E. OUTSIDE GROUNDS AND PREMISES.** The grounds surrounding a food manufacturing or processing plant shall be free from conditions that may result in the contamination of food, food-contact surfaces or food packaging materials such as the following:

1. Improperly stored unused equipment that may attract and harbor insects and rodents.
2. Litter, trash, solid waste and other refuse.
3. Tall weeds and grass in excess of 6 inches in height.
4. Excessively dusty roads, yards or parking lots.
5. Areas around plant that are poorly drained or structures that accumulate rainwater such as trailer back-down ramps adjacent to loading docks.

**F. WATER SUPPLY.** An ample supply of potable water delivered under pressure shall be provided on the premises for drinking, washing of equipment and utensils, supplying toilet and lavatory fixtures, and for other necessary purposes. Potable water supplies shall not be cross-connected to any other supply. Water supply lines connected to processing equipment such as picking tables, bottle/can washers, cookers, retorts, or other similar equipment must have water lines protected against possible back-siphonage or back flow. New private water supplies must be evaluated and approved by sanitarians from the local Parish Health Unit or the regional Environmental Engineering staff and new wells must be registered with the Louisiana Department of Natural Resources.

**G. SEWAGE AND WASTE DISPOSAL.** Sewage disposal and treatment methods must be evaluated and approved by sanitarians from the local Parish Health Unit. Solid and liquid industrial wastes must

be disposed of or discharged in accordance with regulations set forth by the Department of Environmental Quality.

## H. SANITARY FACILITIES.

1. **Toilet facilities.** Each plant shall provide its employees with toilet and associated hand washing lavatory facilities within the plant. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and not open directly into areas where food is exposed to airborne contamination except in the case where double doors are provided or a positive air flow systems are used.
2. **Hand Washing Lavatories.** Facilities for hand washing and, where needed, sanitizing hand dip stations, shall be provided at each location in the plant where good sanitary practices require employees to wash and dry hands, and at least in areas where foods are handled. Hand washing lavatories shall be provided in sufficient numbers to ensure that employees are able to maintain adequate personal cleanliness. Hand washing lavatories shall be supplied with hot and cold running water under pressure with mixer type faucets for adjusting water temperature. Soap and single service disposable towels or forced air drying devices shall be provided at hand lavatories.
3. **Sink Facilities.** Sinks adequate in size and number must be provide within food manufacturing and processing plants for washing utensils and pieces of equipment that are moveable or can be readily disassembled for cleaning and not intended to be cleaned in place. Sink compartments must be large enough to accommodate (not completely submerge) the washing of the largest piece of moveable equipment or utensil. Sinks should be constructed of stainless steel or high-density food grade polymer plastic. Sinks constructed of galvanized steel are not acceptable.
  - a. **3-Compartment Sink:** Facilities engaged in the manufacture, processing and packing of food products must provide sinks with three compartments. Each compartment is to be designated for a specific purpose:

<b><i>Compartment #1</i></b>	<b><i>Compartment #2</i></b>	<b><i>Compartment #3</i></b>
Detergent Wash to remove soil and food residues.	Rinse with clean, potable water to remove detergent solution	Immersion in hot water or chemical sanitizing solution to destroy harmful microbes not removed by washing process (See Sanitary Operations).

Each sink compartment is to be provided with hot and cold running water delivered under pressure. Sinks are to be properly installed and shall be trapped and vented. Each compartment is to be provided with a stopper (cloths are not permitted for this purpose).

Sinks designated for washing or thawing of food or food ingredients shall be designated for that purpose only and shall not be used for cleaning equipment or utensils.

- b. **Utility Sink Facilities.** Food manufacturing and processing plants that use wet mopping for cleaning floor surfaces should provide at least one utility sink **OR** curbed cleaning facility with a floor drain for the cleaning of mops, buckets, pails, scrub brushes or other similar cleaning tools and for the disposal of mop water or similar liquid wastes. The use of lavatories, utensil and equipment washing sinks, or food preparation sinks for this purpose is prohibited.
- c. **Grease interceptor/Separators.** Grease interceptors or separators may be required to be installed in the waste line leading from sinks, drains, or other fixtures in food manufacturing or processing facilities where grease, grit, oil, broken glass, or other viscous or solid substances can be introduced into the drainage system in quantities that can affect line stoppage or hinder sewage disposal. Check with your local parish or city plumbing authority to determine if the installation of a grease interceptor or a separator is mandatory for your specific operation.

## I. SANITARY OPERATIONS.

1. **General Maintenance.** Buildings, floors, walls, ceilings, and other physical facilities of the plant shall be kept in good repair and shall be kept clean. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food, food contact-surfaces and food-packaging materials.
2. **Machinery, Equipment and Utensils.** All machinery, equipment and utensils shall be arranged and installed so as to be easily accessible for cleaning and maintenance and shall be kept clean and in good repair. An ample supply of steam, hot and cold water, sanitizing agent, hoses, brushes or other utensils necessary for proper cleaning of equipment shall be made available. Hose ends or nozzles shall not be allowed to lie on the floor but shall be hung or racked when not in use. Open ends of hoses or food transfer lines shall be capped, plugged or otherwise protected from contamination when not in use. Machinery, equipment and utensils must be designed and constructed so as to be easily cleanable and shall not contaminate food, food ingredients, or packaging material with lubricants, fuels, metal fragments, paint flakes or other contaminants.
3. **Cleaning and Sanitizing of Equipment and Utensils.** Food contact surfaces of equipment and utensils shall be cleaned as often as necessary to avoid contamination of food, food ingredients and food packaging materials.

Food contact surfaces of equipment and utensils used in the processing and packaging of foods subject to contamination by harmful microbes shall be washed with a suitable detergent solution, rinsed with potable water and then sanitized in a manner specified below:

<i>Method</i>	<i>Agent</i>	<i>Strength (ppm)</i>			<i>Temperature</i>	<i>Time</i>
		<i>Food contact surfaces</i>	<i>Non-food contact</i>	<i>Operations water</i>		
Immersion (soak)	Chlorine as hypochlorite	100-200*	400	3-10	75 °F or above	At least 1 minute
Immersion (soak)	Iodine @ pH of 5 or below	12.5-25*	25		75 °F or above	At least 1 minute
Immersion (soak)	Quaternary Ammonium Compounds	200*	400-800		75 °F or above Use only in water w/ hardness of 550 ppm or less	Use in accordance with label specifications
Immersion (soak)	Hot Water				170 °F	At least 30 seconds
Live Steam w/ no additives	Steam					
Rinsing, Spraying, Swabbing	Chlorine, Iodine Solutions	Same as Immersion (soak) method			75 °F or above	At least 1 minute

\* The higher end of the listed range indicates the maximum concentration permitted without a required rinse (surfaces must drain)

Source: 21 CFR 178.1010

Non-food contact surfaces of equipment and utensils shall be cleaned as frequently as necessary to minimize accumulations of dust, dirt, food particles, and other debris.

Equipment and utensils shall be air-dried after washing, rinsing and sanitizing.

All chemical sanitizing agents shall be prepared and applied in accordance with instructions on the product label.

4. **Personnel.** Plant owners and managers shall take all reasonable measures and precautions to ensure the following:
  - a. **Disease Control.** Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, a restrictable or excludable illness, as defined by FDA, or an open lesion, including boils, sores, or infected wounds shall be excluded from any operations which may be expected to result in contamination of food until the condition is corrected.
  - b. **Cleanliness.** Employees shall wear outer garments suitable to the operation that protects against contamination of food, food-contact surfaces or food-packaging materials.
  - c. Employees shall maintain adequate personal cleanliness.

- d. Employees shall wash hands thoroughly and sanitize where appropriate in an adequate handwashing facility before starting work, after each absence from the work station, and at any other times when hands have become soiled or contaminated.
- e. Employees shall remove all unsecured jewelry that may fall into food or equipment and remove hand jewelry that cannot be thoroughly cleaned and sanitized.
- f. Employees shall maintain gloves in an intact, clean, and sanitary condition. Gloves must be of an impermeable material.
- g. Employees shall wear, in an effective manner, hair nets, head bands, caps, beard covers, or other effective hair restraints.
- h. Employees shall store clothing or other personal belongings in an area other than where food is exposed or where equipment and utensils are washed.
- i. Employees shall not eat food, chew gum, drink beverages or use tobacco in any form in areas other than where food and food-contact surfaces are exposed or where equipment and utensils are washed.

**J. TEMPERATURE CONTROL**

- 1. **Holding Temperatures.** Perishable and potentially hazardous foods (including food ingredients) shall be held during storage and delivery at the following temperatures to assure freshness, wholesomeness and highest quality:

<i><b>HOLDING STATE</b></i>	<i><b>MINIMUM TEMPERATURE</b></i>
Cold ( Refrigeration )	Below 45° F
Hot	Above 145° F
Frozen	At or below 0° F

- 2. **Thawing.** Frozen potentially hazardous foods and food ingredients shall be thawed as follows:
  - a. In refrigerated units at an ambient air temperature not to exceed 45° F.
  - b. Under potable running water of a temperature of 70° F or below, with sufficient water velocity to agitate and float off loose food particles to overflow.
  - c. As part of the conventional cooking process.
  - d. In a microwave oven only when the food will be immediately transferred to conventional cooking operations as part of a continuous cooking process or when the entire, uninterrupted cooking process takes place in the microwave oven.

**K. PEST CONTROL.** No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food packaging material. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces and food-packaging materials. Pesticides and rodenticides shall be used in a food processing plant in strict accordance with label directions.



**L. STORAGE PRACTICES.** Food, food ingredients and food-packaging materials shall be stored and handled in such a manner so as not to allow cross-contamination or to interfere with sanitary operation of the plant. Food, food ingredients, and packaging materials should be stored at least 18 inches from walls and 6 inches above floors to allow for proper inspection, cleaning and pest control measures and to allow for movement of air under and around stored food products.

Chemicals such as cleaning compounds, lubricants, solvents, et cetera shall not be stored adjacent to or above food, food contact surfaces or food packaging materials and should be kept in a separate designated room or area. Pesticide compounds should also be stored away from food, food contact surfaces and food packaging materials in a locked cabinet under control of supervisory staff or plant management.

**M. WAREHOUSING AND DISTRIBUTION.** Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of food and the container.

**N. MOBILE FOOD VENDORS.** Persons wishing to operate mobile food or beverage vending units must contact the Parish Health Unit Sanitarian within the parish in which the mobile vending units operate or where the operator is based.

**O. SANITARY CODE COPIES.** Copies of the Louisiana State Sanitary Code are available from the Office of the State Register, Louisiana Administrative Code, P.O. Box 94095, Baton Rouge, LA 70804, Telephone 225-342-5015 (or by visiting this link: <http://doa.louisiana.gov/osr/product.pdf>). The Sanitary Code can also be downloaded from the state website at <http://www.doa.la.gov/Pages/osr/lac/Code.aspx>.

**P. INFORMATION AND INSPECTION SERVICE.** For information or advice on any aspect of operating a food manufacturing or processing facility or if inspection services are needed please contact the appropriate Food & Drug Unit staff person closest to you. A complete personnel index is provided at the following link: <http://www.dhh.la.gov/index.cfm/page/710>.

**Q. FDA FACILITY REGISTRATION AND THE REPORTABLE FOOD REGISTRY.** Following the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA regulations now require that all food-manufacturing facilities register with FDA. Registration can be done online or by completing paper forms. For more information on facility registration, please visit this link (<https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm2006831.htm>) or call this number (1-800-216-7331).

Part of the Food and Drug Administration Amendments Act of 2007 requires that registered food facilities report adverse events that may affect the safety of a food product to FDA. An event that makes it probable that a product will cause serious injury, illness, or death to humans or animals that consume it is deemed a reportable event. More information on the reportable food registry may be found here: <https://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>.