State of Louisiana

Department of Health and Hospitals
Center for Environmental Health Services

Basic Requirements for a Seafood Value-Added Food Manufacturer

This plans review packet is to provide you with the information needed to apply for a Permit to Operate a food manufacturing and distributing establishment. The following can be printed from our website (www.dhh.la.gov/fdu)—they are attached for your convenience:

Please find the following attached to this document **(items in bold need to be submitted for review)**:

1. Guidelines for Prospective Food Manufacturers: Basic Requirements For Prospective Food Manufacturers, Processors, Packers and Repackers.

2. **FD-1B: Plans Review Questionnaire For Food And Drug Establishments**
   - Note that this document requests a **set of plans and specifications for the facility** and these should also be provided to your inspector for review.

3. **FD-1E: Utility No Objection Notice**
   - Provide this form to the local health unit for approval of sewage disposal, water supply and sizing of grease trap.

4. **FD-9(N): Application for Registration**
   - **Label Proofs must be submitted for review via email, by fax or by mail** *before your establishment will be issued a Permit-To-Operate.* The fees and application for the registration will be collected when a Permit to Operate is issued; *do not* send in fees prior to approval of the label(s).

5. Title 51 Public Health – Sanitary Code, Part VI. Manufacturing, Processing, Packing and Holding of Foods, Drugs and Cosmetics. Chapter 1. General Regulations; Chapter 3. Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding Human Food; and Chapter 7. Food Storage Warehouse and Food Salvage Operations; Part IX. Marine and Fresh Water Animal Food Products.
   - **Have your firm's process plan (s) and recall plan available for review at the time of inspection.**

   - Applicable sections from the FDA U.S. Food and Drug Administration: Code of Federal Regulations 21 CFR for all parts of this plans review packet may be found and printed from the FDA Website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

6. US FDA [Food and Drug Administration] requires that all food manufacturing facilities register in accordance with The Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Registrations can be submitted online at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm. Registration of the firm may take place once a Permit to Operate is issued.

7. Under the requirements of §123.6 of Title 21 of the Code of Federal Regulations, any firm processing fishery products (as defined in that section) must have a HACCP (Hazard Analysis and Critical Control Point) plan. Your HACCP plan must be submitted as part of your plans review packet and your firm must have at least one supervisor on staff who has attended a training on seafood HACCP that meets the requirements of 21 CFR 123.10. A schedule of current offerings may be found here: http://seafood.ucdavis.edu/events.html#section3. A copy of the **course completion certificate** must be provided to this office.

Carefully review the Basic Requirements For Prospective Food Manufacturers, Processors, Packers And Repackers. Please submit a set of plans and specifications to this office for compliance review including all items indicated in the plans review questionnaire document.

A Temporary Permit to Operate will be issued after the plans have been reviewed and approved and a pre-operational inspection demonstrates the facility is in compliance with our requirements. All labels must be deemed acceptable for registration before a Permit-to-Operate will be issued. Appropriate fees for both the permit and product registration will need to be collected at the time the applications are completed.

If you wish to discuss any of the basic requirements, or some specific aspect of your proposed food manufacturing or processing operation with an officer or employee of this agency, please don't hesitate to contact this office.