State of Louisiana

Department of Health and Hospitals
Center for Environmental Health Services

Basic Requirements for a Juice Processor

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.
   - **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: www.fda.gov

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 www.fda.gov. Registration of the firm may take place once a Permit to Operate is issued.

7. All juice (as defined in 21 CFR 120.1(a)) sold as juice or for use as an ingredient in other beverages is subject to the juice (Hazard Analysis and Critical Control Point) HACCP regulation. Both intrastate and interstate processors must follow the HACCP regulation. The HACCP regulation requires that processors achieve a 5-log reduction for the microbe identified as the most resistant microorganism of public health significance most likely to occur in the juice.
   FDA provides guidance for industry in the form of this Juice HACCP Hazards and Controls Guidance.

   - Pursuant to 21 CFR 120.24(c), you must carry out the 5-log pathogen reduction, whether it is via a one-step process or a multi-step process, in a single facility, and that facility must be the same facility in which the product is packaged in final form for sale. There are two potential exceptions which can be found in 21 CFR 120.24 (a)(1) or (a)(2). If you do treat your juice at a different facility than the one in which the final packaging is carried out, the treatments applied at the first facility cannot be counted towards meeting the 5-log pathogen reduction requirement.
   - Shelf-stable juices made using a single thermal processing step and juice concentrates made using a thermal concentration process that includes all of the ingredients are exempt from the requirement to include control measures in your HACCP plan to achieve the 5-log pathogen reduction, but a copy of the thermal process from a process authority must be included in your hazard analysis.
     - Information on process authorities may be found at our website here: http://new.dhh.louisiana.gov/index.cfm/page/614
   - Low-acid canned juice and juices subject to the acidified foods regulation are exempt from the requirement to include control measures in your HACCP plan to achieve the 5-log pathogen reduction, but the juice is still subject to the low-acid canned food regulation-LACF (21 CFR Part 113), or the acidified foods regulation (21 CFR Part 114), and

applicable provisions of 21 CFR 108.25 or 108.35, as appropriate, and all of the other requirements of the juice HACCP regulation.
    - If the process is classified as LACF or Acidified the operator will need to attend a Better Process Control School training or other FDA-approved training for the type of product; a schedule of known classes is available at the above website link.
- Processors of low-acid refrigerated juice products, subject to the pathogen reduction provisions of the HACCP requirements of 21 CFR Part 120, but not subject to the low-acid and acidified foods regulation should adhere to the Guidance for Industry document provided by FDA: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices.
    - This guidance does not pertain to low acid and acidified juice products subject to the requirements of 21 CFR Parts 108, 113 and 114. This guidance is intended for processors of refrigerated carrot juice and other refrigerated low-acid juices which can pose a risk of botulism poisoning if juice that is not processed to eliminate or prevent the growth of *Clostridium botulinum* spores that may be present is subsequently stored without proper refrigeration.
- The juice HACCP regulation applies to the processing of any product that may be labeled as 100 percent juice under 21 CFR 101.30 that is sold either as "juice" or for use as an ingredient in beverages. Non-juice beverages that contain juice as an ingredient, e.g., carbonated beverages that contain juice, or fruit flavored drinks that contain juice, are not required to be produced under a HACCP system. However, juice that is used as an ingredient in the non-juice beverage is required to be produced under a HACCP system.

8. Under the requirements of 21 CFR 120.13 any firm processing juice products must have and implement a HACCP plan. Your HACCP plan must be submitted as part of your plans review packet. The individual performing functions listed section 120.13 (a) shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food & Drug Administration, or shall be otherwise qualifies through job experience to perform these functions.
    - Guidance for Industry Standardized Training Curriculum for Application of HACCP Principles to Juice Processing information may be found here: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm072586.htm

9. Under the requirements of 21 CFR 120.6 any firm processing juice products must have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing.

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.