

PROCEDURE FOR OBTAINING A PROCESSED FOOD REGISTRATION (PFR)

California Health and Safety Code (H&SC) Section 110460 requires businesses that manufacture, repack, label, or warehouse processed food products in this State to register with the Department of Health Services, Food and Drug Branch (FDB). The registration acts as the firm's basic health permit to manufacture or warehouse processed food within California.

PFR APPLICATION

The first step towards registration is to submit a fully completed application form with the required fee. You may obtain an application form in the mail by calling the FDB PFR Desk at (916) 650-6516. You should submit your PFR application 30 to 60 days before you would like to start manufacturing or warehousing processed food products.

If your firm is engaged in seafood or juice operations and you are required to implement food safety controls under a HACCP plan pursuant to Title 21 Code of Federal Regulations (CFR) Part 120 or 123, you must pay a fee of \$250 in addition to your base registration fee. This fee is intended to help support the ongoing inspection operations of FDB at those firms that have additional materials, procedures and records to review during inspections.

Each business that registers must also pay a \$100 Food Safety Fee (FSF). The FSF supports FDB's Food Safety Education and Training program for the processed food industry. Businesses that meet the following exemptions are not required to pay the FSF: 1) processed food businesses making less than \$20,000 wholesale gross annual income from their food business, or 2) processed food businesses involved "exclusively" in flour milling or drying or milling of rice. **Please note these exemptions do not apply to the processed food registration fee or the additional \$250 fee.** If your business meets either of these exemptions, you may request the exemption by completing the enclosed Food Safety Fee Exemption Request form and submitting the form with your registration application.

Please keep a copy of the completed application and check for your records. The registration fee is non-refundable and non-transferable to other locations or entities.

The registration is valid for one calendar year from the date of issuance, unless revoked. The business address must be that of the processed food facility, not that of the corporate headquarters. The mailing address can be either that of the facility, corporate headquarters or the firm's branch office (the registration will be mailed to the mailing address). Any incomplete and/or illegible applications will be RETURNED to the applicant. [NOTE: A change of facility/business ownership will invalidate the registration. The new owner must apply for a new registration, prior to the onset of operations.]

INSPECTION

Once your application and check have been processed by FDB, you will be contacted by an FDB Investigator to schedule the pre-registration inspection.

An inspection ensures the business is in compliance with the California Health and Safety Code and the applicable provisions of the Code of Federal Regulations. These include Good Manufacturing Practices, Seafood HACCP Regulations (if applicable), Juice HACCP Regulations (if applicable), and food labeling requirements. The inspection verifies that appropriate operations are employed to ensure that food products and packaging materials are safe and suitable for human consumption. Inspections typically include the following areas:

Business and Product Information will be reviewed to ensure that the business has the infrastructure to employ reasonable controls to prevent foodborne illness, provide training for

employees, identify and segregate ill employees from contact with food, and ensure an environment that meets current standards and requirements. Examples include:

- organizational structure,
- supervision expertise,
- product and ingredient descriptions,
- ingredient sources,
- product distribution,
- recall procedures

Production and Process Controls will be reviewed to ensure that 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,
- access to and use of a process authority,
- process monitoring and quality controls such as those required for HACCP,
- effective use of refrigeration, pH-adjustment, water activity reduction, food additives, commercial sterilization, modified atmosphere packaging, packaging integrity testing, and expiration date validation
- appropriate security measures at the facility

Sanitation Control Procedures will be reviewed to ensure that all food processing and storage is completed without cross-contamination, on clean/sanitized food contact surfaces, following hygienic practices, utilizing potable water, while excluding pests and other contaminants. Examples include:

- sanitation inspections
- cleaning procedures
- sanitizing procedures
- equipment and building maintenance
- pest control program
- material handling and storage procedures

Product Labeling and Advertising will be reviewed to ensure that products are made and held for sale with truthful and accurate declaration of ingredients, including proper declaration of allergens and food additives. Examples include:

- ingredient declaration
- product representations
- nutritional information
- container content representations
- health and nutritional claims

If your firm is found to be in compliance, a PFR certificate will usually be issued within one week of the inspection. If deficiencies are identified during the inspection process, then issuance of the PFR certificate will be delayed until compliance is achieved.

Any inspection that results in violations or deficiencies being discovered, may subject your firm to a reinspection to verify corrective action has occurred. If your facility requires a reinspection to ensure all violations are corrected, you will be charged for the reinspection at a rate of \$100 per hour. Most reinspections require approximately five hours to complete the reinspection in the facility, as well as the investigator's report preparation time and travel time.

After issuance of the PFR, routine inspections will be conducted on an annual basis, or as otherwise indicated. These inspections are NOT scheduled in advance.