



California Department of Public Health Food and Drug Branch



FACILITY INSPECTIONS

The Food and Drug Branch (FDB) conducts regulatory inspections to assure the safety of food products manufactured, processed, stored or distributed in California. The frequency of inspections may be determined by law, risks associated with the food, compliance history, complaints and/or reports of illness. The four most common inspections are listed below:

Readiness Inspections

Readiness Inspections: are conducted to verify compliance with applicable health provisions prior to beginning processing operations. The readiness inspection usually occurs after FDB receives your initial Processed Food Registration (PFR) application. Once the application and fee are received, firms are contacted by an FDB Investigator to arrange for a readiness inspection. Inspection schedules are based on the priorities and workload of the investigator assigned to conduct the inspection. Generally, an inspection will be conducted within 30 days.

During the inspection the investigator will verify compliance with applicable laws and regulations including Seafood and Juice HACCP programs, as required. The investigator will also evaluate whether your facility is appropriate for the planned food activities and that you have established appropriate operations and procedures to ensure food products and packaging materials are safe and protected from contamination.

See "[Preparing For Inspections](#)" for additional information.

Renewal Inspections

Renewal Inspections: FDB inspects food processing facilities based on the risk associated with the operation. Most facilities are inspected annually, however some low risk facilities may be inspected less frequently, and some very high risk facilities may be inspected more frequently. However, regulatory provisions or other factors may require more frequent inspections for specific commodities. Inspections are generally not seasonal and may occur at any time of the year. All inspections are conducted during the normal business hours of the firm and are unannounced. Failure to allow an authorized agent of the Department to inspect your facility is unlawful.

See "[Preparing For Inspections](#)" for additional information.

Reinspections

Reinspections: If significant deficiencies are identified during the Renewal or Readiness inspection, the investigator will discuss these concerns with firm management. The investigator or supervisor may recommend a re-inspection to assure compliance and to verify that corrective actions have occurred. Facilities will be charged a fee of \$100.00 per hour to conduct a re-inspection. The fee includes reimbursement for inspection time, travel and report writing. Most re-inspections require approximately 5 hours to complete.

Complaint, Recall, or Illness Inspections

Complaint/Recall/Illness Inspections: are usually assigned because a food is known to be adulterated or misbranded, or FDB has received a complaint or illness report. These inspections may be conducted at times other than normal business hours when there is a potential for significant, adverse impact to the public. The inspections are generally urgent in nature and frequently involve extensive facility inspections and record reviews.

Notification of Inspections

FDB inspections are not announced or scheduled in advance. However, exceptions are made for new applicants requiring a pre-operational "readiness" inspection and for some consumer/illness complaints.

Preparing for Inspections

Food processors and distributors are responsible for developing controls and processes to produce food that is safe and wholesome. Food processors should also familiarize themselves with the laws and regulations appropriate to the products manufactured or stored in their facilities. These are the standards by which your firm will be evaluated during the inspection. Proper preparation for the inspection can prevent delays in receiving your PFR certificate and save you the additional costs associated with a re-inspection. FDB recommends that you periodically conduct in-house audits to evaluate your company's compliance with health department provisions. Areas to examine include:

- compliance with various health provisions including; the California Health and Safety Code ([Sherman Food, Drug, and Cosmetic Law](#)), California Code of Regulations, Code of Federal Regulations (including but not limited to [Good Manufacturing Practices \(GMPs\)](#), Seafood HACCP, Juice HACCP, and food labeling requirements).
- processes and controls for receiving, storage, manufacturing, sanitation, labeling, advertising and distribution.
- use of food additives, color additives, preservatives, and other chemicals; and control of critical production parameters.

After an inspection

During an inspection, FDB Investigators will document any regulatory deficiencies and present the findings on a Notice of Violations (NOV). Firm management will be advised of the findings during the exit interview. Firm management will be provided an opportunity to discuss any issues and establish a timetable for correcting the violations.

Once the inspection is concluded, the investigator is required to submit a written report of the inspection to his or her supervisor. The report will contain a description of findings, recommended actions and firm management response. Based on the findings of the inspection, investigators will recommend: issuance of a license, certificate or registration; reinspection, or other follow-up action as indicated.

FDB requests that written responses to the NOV include what actions have been taken to address the violations and the timetable for completing the corrections. Corrective Action letters should be mailed to the supervisor listed on the NOV within 10 (ten) working days.

This process is provided in [Chart 1](#).

Questions or Concerns About Inspections

Firms with concerns about the findings of the inspection or those wishing to appeal a regulatory decision by the investigator should contact the supervisor listed on the Notice of Violation.

Chart 1- Application Process

