

GUIDELINES

FOR

HANDLING

REGULATORY

INSPECTIONS

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GUIDELINES FOR HANDLING REGULATORY INSPECTIONS

INTRODUCTION

Food Plant inspections are conducted at several different levels. At the most basic, a food plant must make continuous internal, day to day inspections of the quality and condition of raw ingredients, incoming products, products in process, packaging materials and processing methods.

Self-audits or reviews also include, but are not limited to, monitoring hygiene practices of personnel, plus the condition and cleanliness of the equipment and facility. These ongoing, regular, internal assessments of the food plant allow for the timely correction of actual and potential problems, as well as provide the insurance for the manufacture of a safe and wholesome final product.

At another level, inspections are conducted by regulatory authorities, from county and state agencies to federal involvement by the FDA. These agencies have been given the responsibility and authority to ensure food safety through regulation and inspection. The following pages outline guidelines to follow and what to expect in the event of such an external inspection. Having a plan that includes educating plant personnel about such inspections and a designated team of well informed employees to handle these inspections ensures that the reception of the inspector(s) to the facility will be professional and the review will be conducted in a business-like and orderly manner. This kind of preparation is very much appreciated by the inspector(s) and leaves a favorable impression that may carry through the inspection process.

FDA's AUTHORITY

FDA's authority to inspect records and facilities for violations is contained in Sections 703 and 704 of Title U.S. Code: Federal Food, Drug and Cosmetic Act, as amended 1985. These sections are summarized below:

- Section 703 describes the inspection of records and provides that all records showing the movement of any article in interstate commerce or holding of any article during or after the movement in interstate commerce and all records showing the quantity, shipper and consignee of the article may be inspected. The provisions of this section also state that the above records shall be given only upon receipt of a written request from the inspecting agency in order to prevent the use of any such records in a criminal prosecution.
- Section 704. (a) Provides for the inspection of factories, warehouses, or establishments in which goods are manufactured, processed or held for introduction into interstate commerce or have already been introduced into interstate commerce, or of any vehicle being used to transport such goods, and all permanent equipment, finished and unfinished materials, containers and labeling used therein. Generally, the inspectors are authorized to enter and inspect at reasonable times (normal business hours) and within reasonable limits. For food plants, this generally means an inspection under this section will not extend to records, files, financial data, sales and pricing data, personnel data or research data.

However, FDA has recently established regulations, 21 CFR Parts 123 and 1240, to ensure the safe processing and importing of fish and fishery products (seafood) by adopting a system of preventive controls in accordance with Hazard Analysis Critical Control Point (HACCP) principles. The records associated with the monitoring of the critical control points in HACCP plans may be inspected. FDA is currently proposing similar regulations to ensure the safe processing of fresh cut fruits and vegetables.

- Section 704 (b) After completing the inspection and before leaving the facility, the inspector will provide a written report describing any observed conditions or practices, which in the inspectors judgment, indicate that any food in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed or held under insanitary conditions *whereby it may have been rendered injurious to health.*

The above italicized words are generally known as the *May Clause*. This has been interpreted to mean that only the *potential* for or the *possibility* of contamination or adulteration need exist. Direct or indirect contamination does not have to exist. Inspectors are well trained and take their jobs of protecting the food supply very seriously. They will include in their report conditions likely to lead to contamination or adulteration of the food.

- Section 704 © If the inspector has collected a sample(s) during the inspection process, the inspector is required to provide a receipt describing the sample(s) taken after completing the inspection and before leaving the facility. If a sample(s) is collected during the inspection process and analyzed, a copy of the analysis results are to be promptly furnished to the inspected party.

STATE'S AUTHORITY

The individual States generally mimic the laws and regulations established by the federal government for the protection of our food supply. Some States have made minor changes, but nothing that is considered to be in direct conflict with the intent of the federal laws and regulations. Counties and parishes are typically recognized as direct arms of the State and enforce the laws and regulations of the State they represent. Readers are encouraged to review their State's authority and food protection program for differences that may exist from the federal program. A summary of the State of California's authority is provided as an example.

The state of California has modeled its program after that of the FDA. Its authority to inspect is contained in Section 26230 of the California Food, Drug, and Cosmetic law. Basic authority is also stated in the General Provisions of the Health & Safety Code. The important differences in the State of California's program are listed below:

- State of California inspectors, unlike federal inspectors, are not required to present a written request or *Authorization to Inspect* form when presenting themselves at the facility and before beginning the inspection.
- The State of California, unlike the FDA, will not accept any charges for samples collected during an inspection.

- The State of California does not require its inspectors to split or share samples collected during the inspection process with company representatives. This does not mean that the inspector(s) will not split or share a collected sample if there is an adequate amount available. However, the best practice is for the company's representative to collect a side by side sample(s) whenever possible.
- The State of California is not required to provide the inspected party with a copy of any analysis results of any sample(s) collected during an inspection.. This does not mean that the State of California will not share analysis results, particularly if the inspected party is willing to pay for the analyses. Beyond sharing the inspectors collected sample(s) the inspected party should always send the sample(s) collected by the company representative to an independent laboratory for a duplicate analysis.

California's inspection personnel may inspect any records which have a bearing on whether the food in question may possibly be adulterated, misbranded or falsely advertised or has been or is being manufactured, packed, transported, sold or offered for sale in violation of the law. Generally, inspections do not include records involving financial data, sales data (other than shipping records), pricing data, personnel data (except data on qualifications of technical and professional personnel), or research data.

GENERAL CONCERNS OF REGULATORY INSPECTORS

A comprehensive inspection requires regulatory inspectors to examine thoroughly the interior and exterior of the food processing facility. Inspections may also be limited in scope e.g., re-inspections, sample collection, embargo releases, etc. Although an inspection may initially be limited in scope, inspectors are vigilantly observing employee practices and processing procedures as they walk through the facility and what began as a limited inspection can quickly turn into a comprehensive one.

There are no established rules as to where an inspection must begin. The type of inspection to be performed typically dictates this. Most inspectors begin a comprehensive inspection by following the flow of production from the receiving of raw products and ingredients, through the process, to final product packaging and storage.

Inspectors are looking for anything that may pose a hazard to the food product or its ingredients. The following is a general list of common sense inspector concerns:

- *Personnel Sanitation & Hygiene Practices* - Improper employee behavior or practices, poor personal hygiene, improper attire, work habits conducive to product contamination, or the lack of adequate training or supervision.
- Evidence of rodent, bird or other vertebrate pest contamination on raw incoming product, ingredients, packaging materials, product in process, processing equipment or facility environment (floor, walls, ceiling, etc.).
- Evidence of insects, spiders, mites, or other invertebrate pest contamination on raw incoming product, ingredients, packaging materials, product in process, processing equipment or facility environment (floor, walls, ceilings)
- Dirty, inaccessible for cleaning, or food processing equipment than cannot be cleaned, or food handling utensils.

- Raw commodities or ingredients, water, ice, etc. held under insanitary conditions.
- Insanitary or inadequate personal service areas for employees, such as bathrooms, locker rooms, lunchrooms, etc.
- Sanitary design of the facility including floors, floor drains, walls, ceilings, overhead fixtures, plumbing, processing equipment, etc.
- General plant structure including surroundings or grounds, waste and sewage disposal practices relating to cleanliness and pest exclusion.
- Storing or handling or any packaging materials, ingredients, raw product, in process, or finished product subject to rodent or insect infestation.
- A customized quality assurance program including HACCP plan in place and functioning.
- Documentation and records complete and well organized.

INSPECTION PREPARATION AND CONDUCT DURING THE INSPECTION

A consumer, food product, or employee complaint may prompt an on-site inspection. However, it will generally be as a result of a routine, regularly scheduled visit. Plant inspections are generally scheduled every one to four years. The frequency of inspection may depend on the type of processing operation and/or past inspection results. If serious violations have been noted during past inspections and/or corrective actions have not been outlined or pursued vigorously, one can expect to be inspected more frequently.

- During normal business hours, train your receptionist to directly and immediately alert top management of the presence of any FDA or State representative(s). If an inspector arrives after normal business hours, there should be a procedure in place for advising appropriate company personnel of the inspector's presence. Try not to keep the inspector waiting. However, it is normal to ask the inspector to please wait until the appropriate company personnel can arrive at the facility.
- Once the inspector has been logged or signed in, he/she should be attended as soon as possible.
- Greet the inspector, confirm his/her identity, and accept the "Authorization to Inspect" form, if one is given, and determine the reason for the visit. If an inspection is to take place, determine the type of inspection (limited, comprehensive, etc.) prior to beginning the inspection tour.
- Many firms have developed, with assistance of their legal counsel, a written statement, which can be presented to an inspector during the pre-inspection interview. Two very important items to consider when writing your company inspection policy are:
 1. Will you allow the taking of photographs during the audit?
 2. Will you allow review of records, other than bills of lading from your plant into intrastate or interstate commerce?
 3. Both the *photograph* and *records review* subjects should be clarified up front during the pre-inspection conference.
- Be certain the inspector has the required protective and sanitary equipment prior to beginning the inspection tour.
- Arrange for a knowledgeable individual(s) to accompany the inspector during his/her visit. The following guidelines are suggested for the individual(s) accompanying the inspector:

1. If more than one person is to accompany the inspector, only one individual, by pre-arrangement, should speak on behalf of the company. The other individual(s), representing the company, should serve as a designated record keeper and witness to the conversations between the inspector and the company's designated speaker.
 2. The individual(s) should not serve to guide the inspector, but rather to accompany the inspector wherever he/she wishes to tour.
 3. The accompanying individual(s) should be courteous, businesslike, and knowledgeable about basic plant operations. Questions are to be answered as simply as possible without volunteering any more information than necessary.
 4. The accompanying individual(s) should take detailed notes of the inspection and re-write these notes following each day of a multi-day inspection. The notes are to describe the inspection as thoroughly as possible. Areas inspected and the amounts of time spent there must be included. List the questions asked by the inspector and the replies to these same questions. Also, include anything suggesting the inspector's special inspection interests, etc.
 5. The accompanying individual(s) should take duplicate samples and photographs of any material(s) samples and photographs taken by the inspector. A written receipt for the sample(s) with an exact description (product, size, weight, label or brand, total number, etc.) of each sample(s) collected should be obtained. Duplicate sample(s) should be analyzed for the same conditions or organisms as the agency sample(s).
 6. The accompanying individual(s) should attempt to determine which departments or areas the inspector intends to inspect during subsequent days, and then advise the General or Plant Manager.
- If any deficiencies can be corrected on the spot, or during the course of the inspection, take immediate action. Immediate corrections will reflect very favorably on the company.
 - Samples taken by the inspector should be split with the company representative(s), or duplicate samples should be taken and properly labeled by the company representative(s). Analysis and proper handling of the sample will depend on the type of sample taken, and the object contaminated.
 - The inspector will present a Report of Observations at the conclusion of his/her inspection only if they note discrepancies or potential avenues of contamination.
 - Inspectors will rarely offer advice or relate how competitors may have solved similar problems. They will not enter into lengthy disagreements or discussions once an observation has been written.

POST INSPECTION

The post inspection conference should allow enough time to discuss the inspection and to prepare notes for a subsequent letter to the inspecting agency addressing all the items listed on the Report of Observations. Also, express thanks to the inspecting agency for the inspection and for making you aware of the items requiring correction or attention. Other than any obvious error in fact, it is generally best not to argue with either the inspector(s) or the inspecting agency. Try to list realistic dates of correction if structural modifications are necessary. The letter, the inspector's Report of Observations, and corrections should be reviewed for planning and response by corporate management, and follow the inspection as soon as possible. Although a post inspection letter is not required, it does demonstrate the company's concern and interest, defines corrective action, and will be regarded favorably by the inspecting agency.

