GUIDELINES FOR HANDLING REGULATORY AND INDEPENDENT INSPECTIONS

INTRODUCTION

Food facility inspections are conducted at several different levels. At the most basic, a food facility 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 facility 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.

Facility inspections may be required by buyers as a condition to supply. Buyers require demonstrable commitment to food safety and food quality from their suppliers. Buyers may conduct these inspections themselves or require the facility to contract with an independent third party auditing company to conduct a comprehensive verification audit of operations.

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 facility personnel about such inspections and a designated team of well informed employees to handle these inspections ensures that 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.

AUTHORITY OF INSPECTORS

FDA

FDA's authority to inspect records and facilities for violations is contained in Sections 703 and 704 of Chapter VII – General Authority; Subchapter A – General Administrative (revised/posted November 18, 1998) of the U.S. Code: Federal Food, Drug and Cosmetic Act. Chapter IV – Food (revised/posted 1.20.99). 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 facilities, this generally means an inspection under this section will not extend to financial data, sales data other than shipment data, pricing data, personnel data or research data.

- 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 (c) If the inspector has collected a sample(s) during the inspection process, after completing the inspection and before leaving the facility the inspector is required to provide a receipt describing the sample(s) taken. 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.

Additionally, the FDA is responsible for carrying out certain provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), of which Title III (Safety of Food and Drug Supply), Subtitle A (Food Supply Protection) is particularly relevant.

- Section 303 of the the Bioterrorism Act authorizes FDA to order the detention of food if an officer or qualified FDA employee finds, during an inspection, examination, or investigation, credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals. Requires that the article be labeled or marked as detained and to be removed to a secure facility. A detained article may not be transferred until released or detention expires. Temporary holds at ports of entry for a period not to exceed 24 hours are authorized when an officer or qualified FDA employee has credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals; and the officer needs more time to inspect, examine, or investigate.
- Section 305 requires owners, operators, or agents in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their facilities with FDA, unless the facility is exempt.
- Section 306 requires the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed for inspection to allow identification of immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals.
- Section 307 requires that FDA receive prior notice of food imported into the United States. Most of the prior notice information required by the interim final rule is data usually provided by importers or brokers to the Bureau of Customs and Border Protection

(CBP) when foods arrive in the United States. The Bioterrorism Act now requires that this information also be provided to FDA in advance of an imported food's arrival to the United States.

STATE

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. Readers are encouraged to review their State's authority and food protection program for differences that may exist from the federal program.

SECOND PARTY (BUYER)

A buyer's authority extends from a relationship with the supplier that is usually contractual. Buyers have specific interest in certain products and processes. It is in their interest for their supplier to conform to their requirements for a range of criteria. These include but are not limited to: self-audits, food safety including GMP compliance, quality, HACCP, labeling, packaging and food security.

THIRD PARTY

Third party auditing companies are independent, auditing organizations that are contracted to perform an independent verification on behalf of a facility/company or buyer. Audits are based on compliance with relevant industry laws and regulations. Third party audits are used to learn about the inspection process and to pinpoint potential or actual problems or risks, allowing companies to implement corrective actions.

GENERAL CONCERNS OF 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, quality inspections, HACCP, sample collection, embargo releases, etc. Although a regulatory inspection may begin 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. However, 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. An inspection of monitoring records and other documentation usually follows.

Inspectors are looking for anything that may pose a hazard to the food product or its ingredients. Many of these issues are outlined in 21 CFR Part 110 and are relevant to food facilities. Second and third party audit scopes will vary and may include more quality systems auditing. 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.
- Improper storage, labeling or handling of chemical products.
- 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 facility 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.
- Product labeling compliance.
- A customized quality assurance program including a HACCP plan (if relevant) in place and functioning.
- Written and functioning (challenged) recall/traceback program.
- Written pest control program.
- Self-inspection and monitoring records.
- Documentation and records complete and well organized.

General food security concerns:

- A risk management plan in place and functioning.
- Trained employees and customers.
- Potential hires screened.
- Processing facility secured e.g. the physical boundaries, premises within the plant, and the materials and personnel going in and out of the facility, hazardous materials, energy and water sources.
- Monitored processing system from beginning to end, including any water.

INSPECTION PREPARATION AND CONDUCT DURING THE INSPECTION

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 again. 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. Facility inspections by regulatory agencies are generally scheduled every one to four years, while by buyers and third party auditors generally schedule inspections on an annual or seasonal basis. The frequency of inspection may depend on the type of processing operation and/or past inspection results.

- During normal business hours, train your receptionist to directly and immediately alert top management of the presence of any FDA or State representative(s). Buyers and third party auditors generally have scheduled appointments. If a regulatory 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 and confirm his/her identity. A regulatory inspector may present an "Authorization to Inspect" form. If a regulatory 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 policy 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? If so, consider what may/may not be photographed.
    2. Which records inspectors will be able to review? Be aware of federal and state authority to inspect.
    3. Both the *photograph* and *records review* subjects should be clarified up front during the pre-inspection conference.
- Be certain the inspector(s) follow all the required GMP's, especially wearing protective garments (smocks, hair nets etc.), handwashing, jewelry removal, etc.
- 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 facility 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, anything suggesting the inspector's special inspection interests, etc.
    5. The accompanying individual(s) should take at least duplicate samples and photographs of any material(s) sampled and photographed by the inspector (usually regulatory only). 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 regulatory agency sample(s).
    6. The accompanying individual(s) should attempt to determine which departments or areas the inspector intends to inspect during any subsequent days, then advise the General or Facility Manager of it.
- 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. To avoid sample contamination, ensure that proper sampling procedures are followed.

- The regulatory agency inspector will present a Report of Observations at the conclusion of his/her inspection *only* if they note discrepancies or potential avenues of contamination.
- Other inspectors (buyers, third party auditors) will generally conduct a "closing meeting" summarizing all the deficiencies he/she has found during the audit. If you do not understand any of the deficiencies noted, ask for clarification of the issue(s). The inspector may leave a written report of findings at the end of the inspection, or send a written report to the facility within a short period of time (usually one-two weeks after the inspection).
- 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

A post inspection conference should always be arranged to discuss the inspection, review notes taken, discuss deficiencies noted and assign responsibility for follow-up corrective actions and timelines. The follow-up process may differ depending on whether the inspection was regulatory or not.

Regulatory agency inspection: the post inspection conference should allow enough time 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.

Buyer inspection: a letter should be prepared addressing all concerns raised during the inspection and at the closing meeting. This will reassure the buyer of your concern and interest in their continued business.

Third-party auditing company: once the written report has been received it should be reviewed against the written notes taken during the inspection. While many items should have been addressed during the post-inspection conference, with responsibilities and timelines this is a good time to review and formalize your intended actions. Always keep a written copy of corrective actions, responsibilities and dates of completion with the inspection report. Some 3rd party audit schemes require corrective action documentation to be forwarded to them for certification purposes.