FOOD SAFETY AND SANITATION

Regulatory Overview

Learning Objectives

- Manage regulatory inspections in a manner that best protects your company
- Prepare site personnel for a regulatory inspection
- Respond to findings during a regulatory inspection
- Establish procedures for handling requests by regulators for records access
- Split samples with regulators

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Regulatory Agencies in the United States

There are a number of regulations that impact the food industry. Specific regulations depend on different factors, such as where your facility is located and what types of products you produce. This chapter focuses on United States food safety regulations and regulatory inspections. Environmental, occupational safety, homeland security, and other regulations are not covered in this chapter.

From a federal level, the United States has two agencies, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). The USDA has jurisdiction over meat, poultry, and eggs (breaking and pasteurizing). The FDA has jurisdiction over all other food products intended for interstate commerce, including food-contact substances. There are some exceptions to these products, such as non-specified red meats (bison, rabbits, game animals, etc.) are under FDA jurisdiction and non-specified birds including wild turkeys, wild ducks, and wild geese are also under FDA. There are also some exceptions when certain products, such as pizza, contain less than 3% raw meat or less than 2% cooked meat. These products would also be under FDA jurisdiction.

Companies that fall under USDA oversight include federally-approved meat, poultry, and egg processing facilities that are inspected by the USDA's Food Safety and Inspection Service (USDA FSIS). A federal USDA inspector maintains an office on-site and reviews production procedures, food safety records, and facilities on a daily basis.

Companies that are regulated by the FDA do not have full-time inspectors at the site. Periodic FDA inspections may occur at these sites during normal business hours. These inspections may be routine or because there is a reason to believe a food safety issue is present. Other inspections may be related to specific regulations, such as HACCP inspections for juice and seafood facilities or thermal processing inspections for food that fall under 21 CFR 113. FDA inspections may consist of a single

inspector or a large team of inspectors. FDA inspections can also be contracted out to state regulatory agencies. In these instances, the state inspectors represent the FDA.

FDA-regulated facilities are also subject to state inspections. The specific state department that will conduct these inspections varies, but it is often the department of agriculture. Many states also require food companies to hold a food processing and/or food warehousing license.

Some food companies may also be subject to local city/county health inspections. Food companies should determine which federal, state, and local agencies have regulatory authority over operations at each of their sites.

Federal Food, Drug, and Cosmetic Act

The overarching regulation for the United States is the Federal Food, Drug, and Cosmetic Act (FD&C Act). This set of laws, passed by Congress in 1938, gives authority to the FDA to oversee the safety of food, drugs, and cosmetics. The act has been amended many times, such as the inclusion of the Bioterrorism Act and most recently the Food Safety Modernization Act (FSMA). At the time of this writing, several sections of FSMA were yet to be finalized and final rules had not been issued.

Food companies can violate the law and food products can be in violation of the law in many ways.

1. If food products as manufactured are found to contain any poisonous, harmful, injurious, or damaging substance.
2. Violations of the law can occur under Section 402(a)(3):
   A food shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substances, or if it is otherwise unfit for food.
3. The most often violated section is 402(a)(4):
   A food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

This means legal action can be brought against a food processor if insects, rodents, or other potential sources of contamination have been found by an authorized inspector in or near equipment,

ingredients, or products, even though evidence of contamination was not found in the finished product.

In recent years, cases under this section have been successfully prosecuted and the insanitary condition section has become a routine part of the FDA's procedure to bring about compliance.

Good Manufacturing Practices

Federal guidelines under the Good Manufacturing Practices (GMPs), which are included in the Code of Federal Regulations (CFR), Title 21, Parts 100-199, Sub Part 110, further refine the FD&C Act. These federal guidelines state the legal criteria under which food can be processed or held and are enforced as law.

The current GMPs were promulgated by the FDA under the authority of the FD&C Act. Failure to comply with GMP regulations can result in serious consequences including recall, seizure, fines, and jail time.

The GMPs were written to cover a broad spectrum of food and food-contact substances. They are general in nature and define the controls a food company must use to produce a safe food product. Each food company is responsible for determining how it will meet the requirements of the GMPs. At the time of this writing, the GMPs are under proposed general revisions per FSMA.

Section 110.10 - Personnel

Prohibits personnel engaged in food processing from wearing insecure jewelry, including rings with stones, pendants, earrings, bobby pins, etc. This requirement helps protect the food from foreign material adulteration. Eating, drinking, and tobacco use are prohibited in production areas, and personal articles are prohibited from being stored in production areas.

Section 110.20 - Plant and Grounds

Requires food processors to take proper precautions to reduce the potential for contamination of end products, raw materials, or food packaging materials with microorganisms, chemicals, filth, or foreign material. Where the possibility of product adulteration

exists, procedures must be developed to eliminate potential contamination.

Section 110.35 - General Maintenance

Requires that all poisonous and dangerous cleaning compounds, sanitizing agents, and pesticide chemicals are applied and stored so that food or food packaging material contamination is prevented.

Section 110.37 - Sanitary Facilities and Control

Requirements for plumbing, sewage disposal, and toilet facilities in order to prevent product contamination.

Section 110.40 - Equipment and Utensils

Requires food processing equipment to be designed and constructed in a way to prevent lubricants, fuel, metal fragments, or any other contaminants from contaminating products.

Section 110.80 - Production and Process Control

Requires facilities to take reasonable precautions to ensure that production procedures do not contaminate food with filth, harmful chemicals, undesirable microorganisms, or any objectionable material.

The key word throughout the GMP guidelines is prevention. The entire food safety program must be based upon the prevention of the anticipated potential for food contamination.

Various industry segments and food companies may have to comply with further regulations. Examples include:

1. Regulated HACCP for meat, poultry, juice, and seafood products
2. Thermal processing for facilities that retort product, including but not limited to cans, jars, or other flexible packaging
3. Grade "A" Pasteurized Milk Ordinance (PMO) for dairy companies
4. Federal Meat Inspection Act
5. Poultry Products Inspection Act
6. Egg Products Inspection Act
7. State food regulations
8. Local food regulations

Federal guidance documents are also written by regulatory agencies. Guidance documents are agency statements of general applicability and future effect, other than a regulatory action, that set forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue. Guidance documents represent the agency's current thinking on a topic. They do not create or grant any rights for any person and do not operate to bind FDA, USDA, or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

Handling FDA Inspections

Food companies regulated by USDA are generally better prepared in working with regulatory inspectors since they have on-site inspectors at their facilities. FDA-regulated operations will only experience periodic FDA inspections. Companies that must be registered with the FDA will receive an FDA inspection at least every three years for domestic high-risk operations and at least once every seven years for domestic operations that are not high-risk. FSMA has defined the frequency of inspections for operations that are high-risk and not high-risk. Factors to be evaluated to determine if a food or facility is high-risk include a known safety risk (e.g., pH or water activity), category recalls or outbreaks, the facility's compliance history (recalls or outbreaks), rigor of the facility's hazard analysis and risk-based preventive controls, and/or time since the last inspection.

All individuals responsible for receiving, manufacturing, storing, and distributing food products must be familiar with regulatory laws, the rights and the objectives of the inspecting agency, and the rights of individual food processors. FDA inspections will be unannounced. The FD&C Act gives FDA personnel the right to enter food establishments at any reasonable time. If a plant normally runs three shifts, an investigator has the right to enter at any time under the law. It is unlawful to deny permission for inspection while the plant is in operation. The FDA inspection may consist of a single inspector or a team of inspectors.

Arrival

Upon arrival, all authorized FDA investigators must produce a Form 482 (Notice of Inspection), which they must sign and date in the facility representative's presence. The individual investigator(s) should be required to show proper credentials. FDA investigators should also be informed of company rules. Examples of these rules may be visitor GMP and security policies and the recording device policy. FDA investigators are generally instructed to not sign company specific policies, such as visitor rules or confidentiality policies.

Usage of Recording Devices

The use of recording devices by FDA investigators has become a controversial and rather complex issue. It is suggested that inspectors are informed that recording devices are not allowed in the facility (if this is your policy and it is posted). However, be prepared for most investigators to challenge this policy stating they have the right to use recording devices. It is recommended that the company have a predetermined policy of how this will be handled. If the use of cameras is restricted, the FDA investigator should be instructed to obtain the name and contact information for the firm's legal counsel and the facility representative should inform FDA district management immediately. Today, many companies choose not to challenge the FDA on camera usage.

Form 482 Notification of Inspection

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO
RM 5003 Federal Office Bldg
901 1st Ave
Seattle, Washington 98104

TO

2. NAME AND TITLE OF INDIVIDUAL
Robert K. Thompson, Plant Manager

3. DATE
Jan.30,2000

4. FIRM NAME
Garden City Nut Shellers

5. HOUR
8:30 a.m.
p.m.

6. NUMBER AND STREET
2704 Sellers Street

7. CITY AND STATE & ZIP CODE
San Jose, CA

8. PHONE # & AREA CODE
95131

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
Sidney H. Rogers

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Investigator 057

[1] **Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:**

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs, nonprescription drugs intended for human use or, restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title).* **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination whether there is or may be ground for invoking subsection (e) or subsection (a)(4) of this section. Such regulation or order shall provide that the Secretary deems it to be appropriate, for the examination upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times access to and copy and verify such records.

[2] **Applicable sections of Parts F and G of Title III of the Public Health Service Act [42 U.S.C. 262-264] are quoted below:**

Part F - Licensing - Biological Products and Clinical Laboratories
and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect the establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid which is offered for barter, or exchange in the District of Columbia, or to be sent to any State or possession or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product safety in a particular factory, warehouse, or establishment for electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or tests)* required by section 358(h) are carried out, and (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

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FORM FDA 482 (9/00) PREVIOUS EDITION IS OBSOLETE NOTICE OF INSPECTION
EP

If the FDA investigator takes pictures, plant personnel are advised to:

- Notify the investigator that s(he) is in violation of company policy
- Take photographs of the same issue from various angles
- Take photographs of the investigator taking the picture as evidence that the company policy was violated
- Request, in writing, a copy of all photographs taken by the investigator

Preliminary Discussion

Once Form 482 has been received and credentials have been verified, the investigators should be escorted to a conference room to have a preliminary discussion with the facility team responsible for handling regulatory inspections. This team should be pre-identified and responsibilities of each individual defined. Some companies that are part of large corporations may also require that corporate contacts be notified of the presence of regulatory investigators.

During the initial meeting, it should be determined which areas of the facility the FDA investigator would like to visit. The FDA investigator should also be informed of who the company contact is and that all questions should be directed to that person. This will prevent FDA investigators from questioning or interviewing employees in the facility during the inspection.

Records Access

The preliminary discussion should cover some very specific items. The first order of business is to determine the reason for the inspection. Routine FDA inspections may simply mean your time has come. If it is a routine inspection, the FDA inspectors are somewhat limited in which records they can request. They are limited to only records pertaining to raw materials received via interstate commerce and records of finished products shipped via interstate commerce. There are some exceptions. Facilities that fall under regulated HACCP and thermal processing must provide appropriate records for these requirements as well.

FDA inspectors can also access records in plain sight. Plain sight refers to food safety records located in the facility that are visible during an inspection (e.g., a master cleaning schedule that is posted on a wall in the production area).

If it is determined the inspection is occurring because the FDA has cause or reason to believe a food meets the serious adverse health consequences or death to humans or animals (SAHCODHA) threshold, then this will allow the FDA investigator additional records access. They must indicate which records they are requesting on Form 482 and those records must be provided within 24 hours. They can request records pertaining to the specific food product in question and the FDA investigator can inspect and copy each of these records.

Regulatory Inspection Team

The facility's regulatory inspection team should be comprised of individuals with knowledge of how to handle these inspections. It is recommended that a minimum of two company representatives be available for each FDA inspector. The primary facility contact should be responsible for escorting the FDA investigator and answering any questions that may be asked. The second person will be responsible for taking detailed notes during the inspection. The notes should account for areas of the facility that were visited, questions that were asked, answers that were provided, specific findings, samples taken (environmental, finished product, or raw material), etc. At no time should the FDA inspector be left unattended.

Evidence

The FD&C Act allows investigators to collect evidence in the form of photographs and/or actual samples of raw materials or finished products. It is not uncommon for the FDA to request two samples of each finished product for labeling analysis.

When sampling is undertaken by an investigator, make certain that you understand what analyses will be performed and request that the investigator physically split the sample with you. You will then want to have the same

analyses undertaken by an outside independent laboratory. In the case of labeling reviews, duplicate samples should be sent to the appropriate department for your own internal check.

Recently, FDA investigators have been taking more environmental samples during their inspections. The facility inspection team should note where these samples are taken and what type of analysis will be performed. If the FDA takes environmental samples from a Zone 1 area, it is recommended that all products be placed on hold pending results from the FDA. If a Zone 1 area is sampled, the facility food safety team should discuss what will be done for that production line. Many companies choose to stop production and complete a total sanitation cycle to limit the amount of product that must be placed on hold.

FDA investigators are becoming more detailed during facility inspections and placing more focus on sanitation, allergen control, sanitary design, personnel practices, etc. Issues related to these programs are being documented by FDA investigators. The facility inspection team should be aware of this and review programs and policies to ensure adequate measures are taken to limit the potential for issues to be found during inspections.

Post-Inspection Meeting
At the end of the inspection, the investigator will usually call for a meeting of the individuals ultimately responsible for plant operations. This is a very important meeting and it should not be taken lightly.

Violations of the FD&C Act, the GMPs, labeling, etc., will be covered at this meeting and a Form 483 (Inspectional Observations) will be left behind if the infractions are considered serious. If a Form 483 is issued, the law does not require you to sign the form even if the inspector asks you to do so. There have been cases where a signed Form 483 has been construed as an admission of guilt. It is recommended to merely accept it graciously. If pressed to sign the form, it is suggested to write "I acknowledge receipt".

Follow-up
When a Form 483 is issued, the business receiving the form must respond in writing within 15 business days to report the corrective actions that have been or will be provided for the issues observed. Even if specific items are not corrected, a timeline should be provided to identify when they will be addressed. It is important

Form 483 Inspectional Observations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administation 1141 Central Parkway Cincinnati, OH 45202	January 3-5, 2000 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: John J. Jones, President

FIRM NAME	STREET ADDRESS
Jones Wholesale Groceries, Inc.	550 Main Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Cincinnati, OH 45202	Food Warehouse

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Rodent Pellets were found throughout the warehouse:e.g.
   a) 20 pellets at floor-wall juncture approx.20 feet east of the personnel door located in center of south wall.
   b) 10 old pellets and 2 fresh pellets on a pallet of Gulf View Tomato Juice in slot #18-36.
   c) 75 pellets on pallet of distressed dog food in morgue room.

2. Dead mice were found in 2 locations in the warehouse.
   a) 2 dead mice in snap traps near southeast corner of warehouse.
   b. 1 dead mouse on floor under pallet in slot #18-34.

3. Live mice were sighted on 1 occasion:
   a) 1 live mouse was found in the "catch-alive" trap in NE corner of warehouse.

FOR TRAINING ONLY

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print orType)	DATE ISSUED
	John R. Smith	Investigator	Jan.5,2000

FORM FDA 483 (8/00) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE OF PAGES

to receive a formal response from the FDA that they have received your responses and that they accept or agree to your actual or proposed responses.

Be honest and respectful when dealing with regulatory agencies or investigators, but always remember that everything you say, do, or show them might be held against you. In addition to the forms left at the plant after each inspection, FDA investigators write a report listing their observations and significant events during the inspection and submit it to their supervisors. They often judge the quality of plant programs and include personal comments regarding personalities, attitudes, etc.

Never underestimate the FDA or any other regulatory agency. While it might have appeared that the investigator was not overly concerned about observations made during an inspection, their supervisors, the regional director, or someone at the federal capitol office might decide to take action. Always anticipate possible actions and respond appropriately with corrective actions and prompt responses to any regulatory action.

Regulatory agencies exist to assure consumers that the products you manufacture are safe and not contaminated. But remember that food plants have rights too and you are there to protect them.

Other FDA Regulatory Actions

FDA is responsible for regulating food manufacturers and the food products they produce using inspections as one of their primary tools. If the FDA determines a product is in violation of the law it can pursue further actions against the company and the product.

Warning Letters

Warning letters are issued for various reasons including: actual contamination, positive environmental testing, unsanitary conditions, GMP violations, violations related to regulated HACCP products, misbranding, labeling violations, etc. A warning letter notifies a company about significant violations the FDA has documented during its inspections or investigations. A warning letter is one of the FDA's principal means of achieving prompt voluntary compliance with the FD&C Act.

If a warning letter is issued, management should directly correspond with the FDA to determine what appropriate corrective actions are necessary. Once corrective actions are taken, the company should request formal documentation from the FDA that they agree with the company's actions and the issues have been addressed.

Suspension of Registration

All domestic and foreign producers, packagers, and holders of foods to be used in the United States must be registered with the FDA. The registration requirement began with the Bioterrorism Act and has been amended by FSMA. Each facility must now renew their registration every two years, in even numbered years, between Oct. 1 and Dec. 31. This registration allows the FDA to keep a database of facilities. Your registration number should be considered your license to conduct business in the food industry.

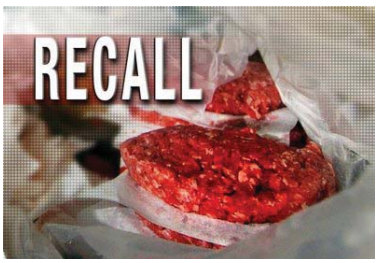
The FDA has the ability to suspend a facility's registration number if there is reasonable probability or reasonable belief a food material meets the SAHCODHA threshold. This belief may be obtained during an actual inspection, product testing, complaints, etc. If registration is suspended, the company would effectively stop production as it is illegal to ship a food material from that facility.

Administrative Detention

The FDA also has the authority to detain a specific food product if there is reason to believe or reasonable probability the food meets the SAHCODHA threshold, is adulterated, or is misbranded. The FDA is able to order a company to detain the specific food product in question for up to 30 days. The food product cannot be shipped and must be held pending further notification by the FDA. If administrative detention occurs, it is advisable to move this product to a segregated area, properly identify its status, and even consider securing that area to ensure no one can accidentally mistake the product and ship it.

Mandatory Recall Authority

FSMA has provided FDA the authority to initiate a mandatory recall if there is reasonable probability or reason to believe the food meets the SAHCODHA threshold. When presented with such information, most food companies would choose



to initiate a voluntary recall. When a food company refuses to voluntarily recall their products, the FDA can mandate the recall, issue civil penalties, and make public notifications.

Reinspections
FDA may reinspect food companies where significant food safety issues were observed, warning letters were issued, or recalls have occurred. FSMA has provided the FDA the authority to collect fees for these reinspections. Fees can be charged for follow-up laboratory testing, inspector preparation time, travel time, and/or time to write a follow-up report.

Reportable Food Registry
On September 27, 2007, the Food and Drug Administration Amendments Act was signed into law. This law amends the FD&C Act by creating a Section 417 - Reportable Food Registry (RFR). The purpose of the Reportable Food Registry is to provide a "reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health".

The RFR requires that a company submit a report within 24 hours when there is a transfer of an FDA-regulated food product outside the company and there is reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals (i.e. lead to a Class I recall situation).

Injunctions
The FDA may use an injunction against a company that fails a reinspection or does not respond appropriately to warning letters that were issued. An injunction asserts a food is adulterated based on GMP violations or that a food was manufactured or held under unsanitary conditions where it may have been rendered injurious to health. The injunction may require the facility in question to close until corrections are made. FDA must reinspect the facility to verify compliance prior to reopening. After reopening, the company remains under court supervision for the foreseeable future.

Park Doctrine and Criminal Liability
The Park Doctrine is based off of a case against a food company that went to the Supreme Court in 1975. The case established the right for the FDA to bring criminal misdemeanor charges against corporate executives. The FDA has the authority to bring felony

or misdemeanor charges against corporate executives or facility personnel for violations of the FD&C Act under that person's control. This can result in imprisonment and/or fines. Recent food safety incidents have resulted in the FDA pursuing cases.

Readiness

Every food plant involved in the receipt of raw materials and the distribution of food will be inspected sooner or later, so they must be prepared. But no matter how prepared a facility is, there is always a bit of uneasiness during regulatory inspections.

Most regulatory inspections are unannounced, which means they seem to always come at the worst time! Regardless, managers must be ready by developing a well-defined product safety program that is understood by all personnel, as well as a well-defined procedure to follow during regulatory inspections.

Procedures that outline regulatory inspections should be established and should identify facility spokespersons and address camera usage, signing inspection forms, collecting evidence, reporting, etc. In addition, the procedures should include the people within the plant or facility who should be notified of the inspection and establish their responsibilities during the inspection period.

Regulatory Overview Reference Card

Use this Regulatory Overview Reference Card as you contribute to your company's regulatory inspection program. When you are ready, proceed to the workshop to apply what you have learned to real-life situations.

Regulatory Overview
Reference Card

Regulatory Agencies in the United States
- USDA
- FDA

UDSA
- Meat, poultry, eggs
- Federal USDA inspector maintains an office on-site at these facilities and reviews production procedures, food safety records, and facilities on a daily basis

FDA
- All other food products, including food-contact substances, not regulated by USDA that are intended for interstate commerce
- Periodic FDA inspections may be routine or because there is a reason to believe a food safety issue is present

Specific Regulations
- Regulated HACCP for meat, poultry, juice, and seafood products
- Thermal processing for facilities that retort product, including but not limited to cans, jars, or other flexible packaging
- Grade "A" Pasteurized Milk Ordinance (PMO) for dairy companies
- Federal Meat Inspection Act
- Poultry Products Inspection Act
- Egg Products Inspection Act
- State food regulations
- Local food regulations

Federal Food, Drug, and Cosmetic Act
- Gives authority to FDA to oversee the safety of food, drugs, and cosmetics

Good Manufacturing Practices
- Legal criteria under which food can be processed or held and are enforced as law
- Section 110.10 – Personnel
- Section 110.20 – Plant and Grounds
- Section 110.35 – General Maintenance
- Section 110.37 – Sanitary Facilities and Control
- Section 110.40 – Equipment and Utensils
- Section 110.80 – Production and Process Control

Handling FDA Inspections
- Arrival
- Usage of recording devices
- Preliminary discussion
- Records access
- Regulatory inspection team
- Evidence
- Post-inspection meeting
- Follow-up

Other FDA Regulatory Actions
- Warning letters
- Suspension of registration
- Administrative detention
- Mandatory recall authority
- Reinspections
- Reportable Food Registry
- Injunctions
- Park Doctrine and criminal liability

Use this Regulatory Overview Reference Card as you contribute to your company's regulatory inspection program. When you are ready, proceed to the workshop to apply what you have learned to real-life situations.

This example **FDA Regulatory Inspection Policy** represents some of the details that companies may wish to include in their own regulatory policies. This example is not all-inclusive of every detail your company may determine is necessary.

Review the example policy and compare it to your company's existing policy to determine if any updates or additions are necessary. Then, proceed to the self-assessment workshop that follows using your company policy to answer the questions.

FDA REGULATORY INSPECTION POLICY

I. PURPOSE
It is the goal of ABC Food Company to conduct its business and distribute food products in accordance with all state and federal regulations. Regulatory inspection procedures will be conducted in accordance with the law.

II. INVOLVEMENT
Regulatory inspection team: Key personnel involved with any regulatory inspection at the facility are the plant manager and food safety manager. An appropriate number of company personnel that are familiar with the inspection procedure guide must be present. There must be at least two company personnel present per inspector.

III. INSPECTION PROCEDURE GUIDE
1. The receptionist will greet the inspector upon arrival at the facility. The inspector should sign the visitors' logbook and be provided a copy of the visitor rules. The receptionist will then contact the appropriate regulatory inspection team member(s).
2. The assigned escort will meet the inspector in the lobby and ask for the proper credentials. The escort will then accompany the inspector to the conference room or acceptable office. A designated spokesperson can be established.
3. The appropriate personnel will ask the nature of the inspection. This could be for several reasons. Examples of reasons would be annual inspections, complaint follow-up, reinspection, etc. A Form 482 (Notice of Inspection) should be presented by the inspector. The inspector can be refused entry if this form is not presented.
4. The appropriate corporate personnel should be notified of the arrival of the regulatory agency.

IV. FACILITY TOUR

NOTE: ABC Food Company does not allow recording or photographic equipment into plant areas.

1. The inspector should be accompanied by appropriate personnel at all times. The inspector should not be left alone for any reason.
2. Written notes of all observations and conversations with the inspector should be taken. Questions will be directed to designated individuals on the regulatory inspection team and should be answered to the point. Information will not be volunteered.
3. If the inspector requests product samples, duplicate samples will be taken. The inspector can be requested to obtain the duplicate sample. If he or she does not, appropriate personnel should take samples in the same manner the inspector uses.
4. Any deficiencies identified during the inspection should be corrected immediately, if possible.

V. RECORDS

ABC Food Company will provide records only pertaining to interstate commerce. The plant manager and/or designated corporate personnel must approve any other records provided.

VI. CONCLUSION OF INSPECTION

At the conclusion of the inspection, a meeting should be held with the inspector to review any observations and deficiencies. A form 483 may possibly be given to plant personnel. The comments on this form should be reviewed. ABC personnel should not sign this form. ABC representatives will document any observations at the conclusion of the inspection.

VII. ADDRESSING VIOLATIONS

1. Discrepancies noted during the inspection should be corrected immediately, if applicable.
2. Corrective action should be instituted as quickly as possible for issues that are not immediately resolvable. (Plant personnel should not give verbal commitments about the timeframe of correction.)
3. If a form FDA 483 is issued by the FDA inspector, a letter of corrective action should be sent within 10 business days of the inspection to the Regional FDA Director. Copies of this letter should also be sent to the appropriate corporate personnel.
4. A formal response should be requested from the FDA Regional Director. The request should include assurance they have received the letter of corrective action and that they are satisfied with the corrective actions provided.

Self-Assessment Questions

1. Who are the individuals on your regulatory inspection team? If three FDA inspectors arrive, do you have at least six trained individuals to accompany the inspectors?

2. Has the receptionist been trained to properly greet regulatory inspectors? Does the receptionist know who is a member of the facility regulatory inspection team?

3. What is your company's recording device/camera policy?

4. If an FDA inspector requests records of interstate commerce, which company records will you provide?

5. How do you take duplicate samples and how will they be documented?

6. Is there a designated notebook that is free of other notes that you can use when taking notes during a regulatory inspection?