WESTERN GROWERS®

FDA Inspections Manual

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NOTICE

This manual provides information and suggested guidelines for Western Growers Association members to follow during food regulatory inspections. The manual represents Keller and Heckman LLP's best efforts to provide information based on current regulations and guidelines, but the requirements and interpretations can change as new regulations and guidance are issued. This manual does not constitute legal advice. The recommendations are not necessarily exhaustive and may not apply in every situation. It is the responsibility of the user of this manual to verify that the recommendations are appropriate for its company and facility. Western Growers does not assume any responsibility for members' compliance with applicable laws and regulations, and recommends that users consult with their own legal and technical advisers to ensure that their procedures meet relevant requirements.

I. INTRODUCTION

The purpose of this manual is to outline suggested policies and procedures that can be adapted for handling food regulatory inspections performed by the U.S. Food and Drug Administration (FDA) and related state food regulatory agencies. (Reference to FDA in this manual is intended to include state and local counterparts, unless otherwise noted.)

This manual provides:

- Guidance for handling food inspections at your facility
- A training reference tool for employees responsible for handling food inspections
- Information regarding a company's rights and an inspector's legal authority during a food inspection

The goal of a food inspector is to determine a company's compliance with regulatory requirements or the cause of a possible violation. This manual outlines rights and duties, so that employees can make informed decisions, during an inspection, on the basis of company policy and applicable law, or can notify senior management and legal counsel of issues that may require further discussion within the company before decisions are made. The company's policy should provide clear direction to employees and should also include the flexibility to select appropriate courses of action, depending on the facts.

A. The Laws

The Federal Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. §§ 301 et seq. is the primary food law of the United States, and is administered by the Food and Drug Administration (FDA). The FD&C Act regulates foods other than meat, poultry, and egg products, which are regulated by the United States Department of Agriculture (USDA). In addition, the states have enacted laws modeled on the FD&C Act.

These laws are intended to ensure that foods are pure and wholesome, safe to eat and produced under sanitary conditions, and that all labeling and packaging is truthful, informative, and not misleading or deceptive. This is achieved by requiring growers, shippers, processors, manufacturers, packers and warehouses to meet minimum safety requirements, to document compliance in records, and to submit to food inspections by regulatory agencies, as authorized by law. The FD&C Act also permits FDA to commission state agencies to carry out examination and investigation functions for FDA. And of course state and local agencies are responsible for enforcing their own food safety laws.

The FD&C Act and corresponding state and local safety and labeling laws impose both general and specific duties on the industry. Generally, these laws prohibit the production and distribution of adulterated or misbranded food products.

Food may be considered adulterated for a number of reasons. A food is adulterated, for example, if it contains any poisonous, deleterious, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Also, food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. If insanitary conditions are found at the farm level, at a produce processing facility or at a warehouse, all products grown, processed or stored during the time these conditions existed are "deemed to be" adulterated. It is not necessary to show actual contamination; inspectors need only show that the food may have become adulterated due to the insanitary conditions. The term "misbranded" includes products with false or misleading labeling, with labeling lacking required information, or with material information omitted, including mandatory allergen labeling.

FDA's primary food inspection authority is found in Section 704 of the FD&C Act, which covers any establishment in which food is manufactured, processed, packed or held for introduction into interstate commerce or after such introduction, and any vehicle used to transport food in interstate commerce.

The Food Safety Modernization Act (FSMA), which amended the FD&C Act in January 2011, significantly expanded FDA's inspectional authority and imposed many new substantive requirements. FSMA shifts the focus for food safety from detection by regulators to prevention and correction/destruction by industry. Moreover, FSMA requires FDA to greatly increase the frequency of inspections, both domestic and foreign.

A number of FSMA provisions apply only to FDA registered food facilities, which generally exclude farms (depending on the scope of the activities). For facilities subject to FSMA requirements, FDA inspectors can request a wide range of records even during a routine inspection, including food safety plans (if required). Companies should be knowledgeable about the records requirements in order to respond appropriately to FDA's requests. For records that are required to be maintained by a company, a failure to properly document, date and sign information will likely be treated as a violation. In the absence of appropriate records, FDA can also question whether the safety activities ever took place, which could have recall consequences.

When follow-up reinspections are indicated at a registered food facility, due to violations noted during an inspection that are materially related to food safety requirements, companies will be charged a fee to cover FDA's reinspection-related costs, including administrative expenses in connection with arranging, conducting and evaluating the results of reinspections. The fees are imposed on an hourly basis per FDA employee, including travel. The fees are higher for foreign facilities. The fees for fiscal year 2018, for example, are $248 per hour/per inspector for domestic reinspections and $285 for foreign reinspections.

Other FSMA statutory provisions expressly apply to farms. For produce safety, regulations establish science-based minimum standards for the safe production and harvesting of fruits and vegetables that are raw agricultural commodities (RACs). The standards include agricultural water quality, soil amendments, temperature controls, and animals in the growing area.

In the past, FDA conducted farm inspections mainly when investigating foodborne illness outbreaks and findings of adulteration (even in the absence of reported illnesses). Now, however, FDA intends to increase the frequency of farm inspections, including on a routine basis and often with no prior notice.

There is an exemption for direct farm marketing. A farm is exempt from the produce safety requirements in a calendar year if, during the previous three-year period, the average annual monetary value of the food sold by the farm directly to qualified end-users exceeded the average annual monetary value of food sold by the farm to all other buyers, and the average monetary value of all food sold during that period was less than $500,000, adjusted for inflation. For purposes of this exemption, qualified end-user means

a consumer of the food (not a business) or a restaurant or retail food establishment that is located in the same state or not more than 275 miles from the farm. The direct farm marketing exemption does not, however, preempt state, local, county or other non-federal laws regarding the safe production, harvesting, holding, transportation and sale of fresh fruits and vegetables. And as a practical matter, many customers will only buy from farms and other suppliers that agree contractually to comply with FSMA standards, even if the operation is eligible for an exemption from FSMA requirements.

The direct farm marketing exemption may be withdrawn by FDA in the event of an active investigation of a foodborne illness outbreak that is directly linked to an exempt farm, or if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or harvested at such farm. 21 U.S.C. § 350h(f)(3).

The FD&C Act authorizes the following enforcement tools to address violations:

1. Injunctive relief against future violations
2. Seizure of products
3. Administrative detention if FDA has reason to believe a food is adulterated.
4. Mandatory recall (if a company will not agree to a voluntary recall) when FDA has determined there is a reasonable probability that the food is adulterated and will cause serious adverse health consequences or death.
5. Criminal prosecution of the company and the individuals responsible for the violation, including on a strict liability basis (meaning that prosecutions may be brought without proof of intent to commit a violation under the FD&C Act or even knowledge of a violation.

Also, most states may "stop sale" of violative products. For less serious violations, FDA can issue warning letters seeking to correct violations. Although voluntary recall is not formally covered in the FD&C Act through binding regulations (there are just guidelines), recall has long been the most common and efficient way for FDA to have violative products removed from the market.

B. The Regulations

FDA's authority during a food inspection is, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, to:

- Enter, at reasonable times, any factory, warehouse or establishment in which food is 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 in interstate commerce;
- 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.

Prior notice to a company of an impending inspection is not required. There is no question that an inspection during normal business hours is a reasonable time, although it may be difficult to deny a food inspector access during any operating hours for companies that have multiple shifts. But as a practical matter, unless there is an urgent matter, food inspectors will generally seek to inspect during normal business hours.

It is generally agreed that a food inspector has the authority to take samples, including products, ingredients, water, food contact packaging and labels. When there is sampling, it is recommended that a duplicate sample be taken by the company. In recent years, FDA has focused to a great extent on

environmental monitoring, to determine whether pathogens have become established at operations or whether any positives are likely due to transient contamination from ingredients, employees, or equipment, which would probably be eradicated at the next cleaning and sanitation. FDA has noted that many major food illness outbreaks seem to be linked to operations at which pathogens had become established, and therefore an important food safety goal for FDA is to identify operations which harbor pathogens so that aggressive efforts can be undertaken to control environmental contamination. FDA may take hundreds of environmental swabs during an inspection.

It is generally inadvisable to run tests of the company's samples unless FDA gets positives and there is reason to believe that those results may be inaccurate. Decisions about whether and when a company should test its own samples taken during an inspection depend on the facts, and require careful consideration.

The inspector may inspect areas where products are stored, processed, or packaged, as well as storage areas for packaging and labeling. However, inspection authority does not extend to any other area of the plant. So, for example, access to offices and other areas not related to food processing or storage can be restricted.

It is unclear, under the law, whether FDA may conduct a warrantless inspection of a food establishment. But as a practical matter, virtually all FDA inspections are conducted with the consent of the company, making a warrant unnecessary. And refusal to permit a warrantless search is generally inadvisable anyway, as FDA should have no difficulty obtaining a warrant.

C. The Types of Inspections

Inspections can be comprehensive or directed. A comprehensive inspection covers everything subject to FDA jurisdiction. It may be scheduled in advance but often inspections are unannounced . A directed inspection is often triggered by information obtained by FDA regarding a potentially significant food safety problem, and covers specific issues. Reasons for a directed inspection include test results, a recall, an illness outbreak which may be linked to a company, a Reportable Food Registry filing, consumer complaints, an adverse event report, a reinspection based on previous findings of violations, a recall effectiveness check, or a criminal investigation. General guidance to food inspectors can be found in chapter 5 of FDA's Investigation Operation's Manual (IOM) available at, http://www.fda.gov/ICECI/Inspections/IOM/ucm123287.htm.

II. PLANNING AHEAD

It is very important to prepare in advance for an inspection. With proper planning, your company's representatives will be in a position to interact with the inspector in a knowledgeable manner, demonstrate the company's dedication to providing safe food products, and protect the company's rights to safeguard its confidential information and to be free of excessive government interference.

A. Establish an Inspection Team

The food inspector will usually arrive without prior notice. To ensure that a company is prepared and properly represented during all food inspections, a company should establish receiving procedures and an Inspection Team as part of the program for conducting inspections. At least two employees—and sufficient alternates—should be part of the team, with one to take notes and the other designated as the Company Contact.

- The Inspection Team, headed by the Company Contact, is responsible for:
- Greeting the inspector
- Participating in the opening (pre-inspection) conference
- Accompanying the food inspector during the actual inspection, taking notes and parallel samples, providing requested records and answering questions as appropriate
- Participating in the closing (post-inspection) conference

Choose a Support Team (e.g., plant manager, quality assurance director, etc.) to be notified that an inspection is taking place so that they can assist before and during the inspection.

The ideal situation would be to have the Inspection Team present at the plant during all normal operating hours or available on an "on-call" basis within short traveling time of a plant. If this is not practical, there should be is an employee at the plant, at all times, who is properly instructed on how to control the situation until the Inspection Team arrives to oversee the inspection.

B. Establish Policies

The Inspection Team and Company Contact are responsible for protecting your company's right to protect its trade secrets and other confidential information, and possibly other rights.

For example, the inspection may include areas of the plant in which trade secrets are maintained. Therefore, employees responsible for handling a food inspection should have a clear understanding, in advance of any inspection, about what trade secrets exist within the facility.

1. Know Your Rights

In addition to incidental exposure to trade secrets, FDA and state agencies may encourage their inspectors to request information to which they are not legally entitled. An inspector may attempt to put an employee under psychological pressure to comply with a request in order to demonstrate that the company has "nothing to hide." An inspector may even indicate that non-compliance with the request may be considered a "refusal to permit inspection." Therefore, those employees responsible for handling the inspection should be in a position to handle such requests in a diplomatic and knowledgeable manner, consistent with an understanding of the law company policy.

a. Documents Which Must Be Disclosed

Certain documents must be disclosed to a food inspector, regardless of the type of inspection.

Be sure your team is familiar with the records that must be provided on request, the circumstances under which they are to be disclosed, and where they are located at your facility.

i. Receipt of Food Products Shipped in Interstate Commerce

Shipping records covering receipt of food products shipped in interstate commerce technically must be made available to an FDA inspector for review and copying, in order to establish jurisdiction, but you can ask for a written request from the inspector specifying the nature or kind of food to which the request applies. The reason to ask for a written request is that no information obtained by FDA pursuant to a written request, including any evidence which is directly or indirectly derived from the shipping records disclosed, may be used in a criminal prosecution of the company or its employees. This defense is not available unless FDA's request is in writing. Accordingly, it is a good practice to get a request for shipping records in writing.

ii. Records under FSMA

Prior to FSMA, FDA had very limited records access authority during a routine inspection, including interstate shipment records to establish FDA's jurisdiction, as discussed above. That said, FDA has long asserted that it may have jurisdiction even if there is no evidence of interstate commerce concerning the products, such as shipments of ingredients and equipment or another impact on interstate commerce.

Under FSMA, however, FDA may review and obtain copies of many records that food companies are required to maintain, even in the course of a routine inspection, if the appropriate criteria for access are met. The specific recordkeeping and records access requirements depend on which FSMA regulations are applicable to a company's operations, such as Hazard Analysis and Risk-Based Preventive Controls (HARPC), Current Good Manufacturing Practices (CGMPs), Produce Safety, Foreign Supplier Verification Program (FSVP), Sanitary Transportation, and Intentional Adulteration. Thus, under FSMA, inspections may involve an intensive audit of records.

The key routine records required to be maintained under FSMA, and the traceability records that must be provided under Bioterrorism Act and FSMA provisions in the event that FDA has serious food safety concerns about products or conditions, are summarized below.

Hazard Analysis and Risk-Based Preventive Controls

FDA registered food facilities are required to develop a written food safety plan under HARPC, unless an exemption applies. The plan must identify and analyze known or reasonably foreseeable hazards that could affect food manufactured, processed, packed, or held at the facility (including hazards that occur naturally or may be unintentionally introduced, as well as intentionally introduced hazards). The plan must also include records that document: the monitoring of preventive controls; corrective actions; validation (of monitoring, corrective actions, calibration of process monitoring and verification instruments, product testing, environmental monitoring, records review, and reanalysis), as well as records that document a supply-chain program and applicable training for the preventive controls qualified individual. HARPC facilities also must establish a written recall plan for any food with a hazard requiring a preventive control.

Required records must be retained at the facility for at least two years after the date they were prepared. Records that a facility relies on during the three-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption must be retained as long as necessary to support the facility's status during the applicable calendar year. Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for

at least two years after their use is discontinued.

Current Good Manufacturing Practices

Under FSMA, previously voluntary Current Good Manufacturing Processes (CGMPs), at 21 CFR Part 110, were revised and are now mandatory requirements, at Part 117. Farms may comply with Part 117 CGMPs or similar requirements in Part 112 under Produce Safety, depending on the type of operation. The CGMP regulations address personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels.

All facilities that manufacture, process, pack, or hold food for consumption in the United States are subject to the CGMP requirements unless an exemption applies. Thus, even if a facility is exempt from HARPC, it may still need to comply with CGMPs. There is no express regulatory requirement to have policies and activities demonstrating compliance with mandatory CGMPs be documented in writing, but as a practical matter, FDA would have no way of determining compliance without reviewing records showing compliance with Standard Operating Procedures (SOPs) that address CGMP requirements.

Training is required under Part 117 to ensure that all individuals who manufacture, process, pack, or hold food subject to CGMPs are qualified to perform their duties. Each individual must be a qualified individual, with education, training, or experience (or a combination) necessary to produce clean and safe food as appropriate to the duties, and must receive training in principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's duties. Responsibility for ensuring compliance must be assigned to supervisory personnel who are qualified or to oversee this training. Records that document the required training, such as the date of training, a description of the training, and the name of the person trained, must be maintained for at least two years.

The Preventive Controls for Human Foods regulations, including subparts pertaining to Hazard Analysis and Risk Based Preventive Controls and Current Good Manufacturing Practices, may be found in Title 21 Code of Federal Regulations (CFR) part 117. The most up-to-date version of 21 CFR part 117 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

Produce Safety

There are recordkeeping requirements associated with a number of activities concerning Produce Safety include: agricultural water, biological soil amendments of animal origin (BSAAO), personnel training (such as date of training, topics covered, and persons trained); and equipment (such as date and method of cleaning and sanitizing of equipment used in harvesting, packing, or holding activities), and sprouts.

Generally, records must be kept at least two years past the date the record was created. Records that a farm relies on during the three-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption (based on average monetary value of all food sold and direct farm marketing), must be retained as long as necessary to support the farm's status during the applicable calendar year. Records related to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to

analyses, sampling, or action plans, is discontinued.

The Produce Safety regulations may be found in Title 21 Code of Federal Regulations (CFR) part 112. The most up-to-date version of 21 CFR part 112 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

Foreign Supplier Verification Program (FSVP)

Importers, as defined under FSMA, must establish and follow written procedures to verify that they only import food from approved suppliers, that the food was produced in a manner that provides the same level of public health protection as HARPC or Produce Safety, as appropriate, and that the imported food is not adulterated and not misbranded (with respect to allergen labeling). FDA did not mandate specific activities that must be conducted to verify the safety of imported food, but FDA's examples include: (1) onsite audits of foreign suppliers; (2) sampling and testing of food; and (3) review of the foreign supplier's relevant food safety records.

Records of all foreign supplier verification activities must be documented and maintained by the importer, including records regarding the hazard analysis, supplier evaluation and approval program, supplier verification activities, and any corrective actions taken to address any identified food safety problems. Any records relevant to an FSVP must be made available promptly to FDA upon request, and must be maintained for at least two years after their creation date, or for at least two years after their use is discontinued, whichever is longer. Offsite storage of records is permissible, provided that such records can be retrieved within 24 hours. Records can be maintained in an electronic format, and are considered to be located at a foreign facility if they can be accessed from that facility.

The Foreign Supplier Verification Program regulations may be found in Title 21 Code of Federal Regulations (CFR) part 1 subpart L. The most up-to-date version of 21 CFR part 1 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

Sanitary Transportation Rule

The extent of recordkeeping requirements under this rule depends on whether a company is acting as a shipper, loader, carrier, and /or receiver. The primary recordkeeping requirements apply to

shippers and carriers. The regulations generally require a shipper to provide a written document specifying the conditions that carriers (and loaders, where necessary) must meet in order to ensure that food is maintained under sanitary conditions, such as design requirements, cleaning procedures, and temperature requirements (including pre-cooling), as applicable. Delegation of responsibilities for conducting food safety procedures may be accomplished through a written agreement between the shipper, the carrier, or another party covered by the regulations.

With respect to carriers, there are mandatory recordkeeping requirements for training personnel to provide an awareness of potential food safety problems that may occur during transportation. Records must be maintained for a period of 12 months beyond the last effective date of those records.

The Sanitary Transport of the Human and Animal Foods regulation may be found in Title 21 Code of Federal Regulations (CFR) part 1 subpart O. The most up-to-date version of 21 CFR part 1 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

Intentional Adulteration

Facilities subject to HARPC are required to prepare and implement a written food defense plan to mitigate the risk of intentional adulteration. Upon completion of a vulnerability assessment, companies must develop a written plan that identifies vulnerabilities and actionable process steps (if any), mitigation strategies, and procedures for food defense monitoring, corrective actions and verification. A reanalysis is required every three years or when certain criteria are met, including mitigation strategies that are determined to be improperly implemented. Facilities are required to maintain documentation of personnel training for those assigned to vulnerable areas, and facilities must maintain records for food defense monitoring, corrective actions, and verification activities. The food defense plan must be stored onsite at the facility. Records must be retained for at least two years after the date of preparation.

Exemptions include farms as defined under FSMA, the holding of food except in liquid storage tanks, and the packing or labeling of food where the immediate food container remains intact.

The Intentional Adulteration regulations may be found in Title 21 Code of Federal Regulations (CFR) part 121. The most up-to-date version of 21 CFR part 121 can be found by going online to the Electronic Code of Federal Regulations at: www.ecfr.gov.

Traceability Records

The Bioterrorism Act of 2002, which amended the FD&C Act, applies to companies that manufacture, process, pack, transport, distribute, receive, hold or import food in the United States, and requires covered companies to establish and maintain records to facilitate traceability, through the identification of the immediate previous sources and immediate subsequent recipients of food, in order to address credible threats of serious adverse health consequences or death to humans or animals ("SAHCODHA" risk). Retail food establishments that distribute food to consumers are exempt from establishing and maintaining records as to the immediate subsequent recipients (consumers). Retail food establishments that distribute food to non-consumers must only maintain immediate subsequent recipient information if such information is reasonably available. Exemptions include farms, restaurants, persons that manufacture, process, transport, pack, distribute, receive, hold or import food that is regulated exclusively by USDA, and foreign persons (except those who transport food). FDA can seek these traceability records if it has

a reasonable belief that an article of food is adulterated and presents a SAHCODHA risk.

Under FSMA, FDA may also access such records if FDA believes there is a reasonable probability that a food could cause serious harm. FDA can inspect all records relevant to determining whether the suspect food presents a serious food safety risk, including records for "related" products, if FDA reasonably believes that the other products are likely to be affected in a similar manner, such as having been produced on the same production line without a sanitation between runs, or using the same ingredient that may be the cause of adulteration.

Also under FSMA, FDA is authorized to request records from farms, during an active foodborne illness outbreak investigation or if necessary to protect the public health and prevent or mitigate a foodborne illness outbreak, to identify potential immediate recipients, other than consumers, of food if FDA reasonably believes such food is adulterated, presents a SAHCODHA risk, and was adulterated.

High Risk Foods

FSMA authorizes FDA to publish a list of "high risk" foods, based on known safety risks including history and severity of outbreaks, the potential for microbiological contamination due to the nature of the food and other factors, and to impose new recordkeeping requirements for high risk foods" (with exceptions), so that recipients can be identified quickly in order to prevent or mitigate a foodborne illness outbreak. At the time this manual was issued, however, FDA had not published a list of high risk foods.

2. Put Policies in Writing

We recommend putting all of your policies in writing in a manual so that the Inspection Team can point to them during an inspection.

For example, if the inspector requests confidential information which the Company is not required to disclose, the Company Contact could respond along the following lines:

"The information you seek is confidential. Company policy, based upon the advice of legal counsel, prohibits me from disclosing that information. However, if you wish to pursue the matter, you may submit a written request to me, the Company Contact, explaining why you feel you need the

information, and I will forward it to the appropriate personnel for their consideration."

The Inspection Team member can then show the written policy to the inspector.

3. Sample Policies

The following samples are provided for your consideration. Appropriate company personnel and legal counsel should be involved in deciding on policies.

The Inspector Must Be Escorted at All Times

Sample policy:

The Company Contact and other appropriate members of the Inspection Team must accompany the inspector throughout the entire inspection period. This will help ensure that the inspector does not accidentally end up in an unsafe situation, contaminate food, inadvertently examine confidential data, cause a significant interruption of operations, or engage in unauthorized conversations with employees. If two inspectors are involved and decide to work independently, an Alternate Company Contact and Inspection Team member will escort the second inspector.

Only Designated Personnel May Respond to Questions and Requests

Sample policy:

The inspector will be instructed that all questions should be addressed to the Company Contact or other designated company representatives. The inspector is not permitted to conduct private employee interviews on company property. Employees are reminded that they are not permitted to respond to the inspector's questions unless authorized by the Company Contact.

Confidential Treatment for Incidental Exposure to Trade Secrets

Sample policy:

Confidential treatment for all confidential information obtained from areas of the plant that contain trade secrets should be orally requested and confirmed in writing to the Investigator before the close of the inspection.

Disclosure of Information, Documents, and Other Records

Sample policy:

Except when authorized by company policy or a supervisor, Inspection Team members will not permit the inspector to have access to or to obtain any confidential information. The following information is considered confidential:

- ☐ Corporate, unit, or department budgets or spending authority
- ☐ Corporate organizational structure
- ☐ Names or titles of any unit or corporate officers
- ☐ Names or titles of plant management

Affidavits and Similar Documents

Sample policy: The inspector has no legal right to require the execution of an affidavit or any other document. Therefore, all employees should refuse to prepare or sign any document requested by the inspector, although documents should be reviewed before accepting them.

Sound Recording Equipment

Sample policy: The inspector is not authorized and, therefore, not permitted to take a tape recorder

or other sound recording equipment beyond the reception area.

Photographic Equipment

Sample policy: The inspector is not entitled and, therefore, not permitted, to take photographic equipment beyond the reception area. This includes cell phones with photographic capability.

Inspector's Compliance with the Company's Health and Safety Rules

Sample policy: The inspector is expected to comply with all of the company's safety and health rules at the facility being inspected and must wear and use appropriate protective clothing and equipment.

Sampling

Sample policy: Upon providing a written receipt (Form Fd-484 shown in Appendix B), and compensation if requested, the inspector may take samples of products, ingredients, packaging, and labeling. Compensation is typically requested only if a large number of samples is collected. If sampling is performed, these procedures are to be followed:

- ☐ The Company Contact will arrange for an employee familiar with sampling techniques to accompany the Contact and the inspector to examine the inspector's techniques and to perform sampling on behalf of the company.
- ☐ The employee will determine and note the sampling procedure and technical instruments or equipment the inspector is using.
- ☐ The employee will ask the inspector if these procedures and equipment are formally approved by the agency and note his or her response.
- ☐ The employee will ask the inspector when and by what procedures the equipment was last calibrated and note his or her response.
- ☐ The employee will note the number of samples taken, when they were taken, and the operations and locations sampled.
- ☐ The employee will ask the inspector to take two of each sample. The second sample will be retained by the Company Contact.
- ☐ The employee will use company test equipment to take samples, in addition to the two taken by the inspector, duplicating the procedure used by the inspector and, where appropriate, using an alternative procedure which would provide similar data.
- ☐ The Company Contact will cause all samples to be labeled in a manner that will permit identification and will ensure that they do not become lost or contaminated.
- ☐ Samples will be retained for one year unless a decision is made by the company to have the samples analyzed.

C. Be Certain You Have an Adequate Safety Program

Ensure that your company's food safety program complies with current legal requirements, and reevaluate it regularly. Confirm that your records are up to date and accessible if needed. Confirm that you can separate confidential information from non-confidential information.

D. Establish Sampling Protocols

During the inspection, a company should, within reason, be able to duplicate every testing procedure or sampling procedure performed by the inspector. Therefore, the appropriate sampling equipment should be

on hand and in good working order with all necessary supplies.

The Inspection Team should be aware of the status of any previous food inspections. All reports from prior inspections will be on file with the inspecting agency and the inspector may ask to see any areas noted in the report as needing correction.

A follow-up inspection should be handled by company personnel according to the same procedures used during the initial inspection. The Company Contact should be familiar with the company's report on the initial inspection and know about the conditions noted as possible violations and how they have been handled or corrected.

E. Conduct Drills

The company should conduct practice drills before an inspection occurs, using the teams and policies the company has selected. Ensure that relevant personnel know the answers to the following questions:

When an inspector calls to schedule a visit —

- Who should take the call?
- Who else should be notified?
- What other actions should be taken right away?

When an inspector arrives at the facility —

- What should the receptionist do?
- Who else should be notified immediately?
- What other actions should be taken right away?

If an inspector asks to see records —

- Who should take the request?
- Which records are permissible or impermissible to disclose?
- When should a supervisor be notified?

If an inspector asks to take samples —

- Who should take the request?
- Who else should accompany the inspector and witness the sampling?
- Who from the company should also take samples? When should a supervisor be notified?

If an inspector sees documents or a part of the operation not required to be disclosed —

- What assurances regarding confidentiality should be obtained? By whom?
- When should a supervisor be notified?

What could or should be done in these scenarios?

- The designated Company Contact and the alternate are unavailable the day of the inspection.
- The inspector arrives after normal working hours. The inspector refuses to wear required safety gear.
- The inspector asks about items noted for improvement in previous inspection reports.

- The inspector pressures an employee to reveal information not required for disclosure.
- An emergency occurs during the inspection:
  - ☐ Electrical blackout
  - ☐ Fire or security alarm
  - ☐ Earthquake or severe weather
- Medical emergency for a team member or the inspector
- The Inspection Team does not have key access to rooms where required records are kept.
- The inspector overhears employees talking about a recent safety violation.

The issuance of a formal notice of alleged violations is serious. It is very important, however, not to let the desire to have a successful food inspection result in illegal actions, such as lying to an inspector or falsifying or destroying records.

III. DURING THE INSPECTION

Two important principles in handling a food inspection are:

1. Make sure you are adequately prepared.
2. Do not take any actions which would elevate a relatively minor violation into something more serious.

The previous material has dealt with the first point. Preparation, as in anything else, is important. The issuance of a formal notice of alleged violations is serious. It is very important, however, not to let the desire to have a successful food inspection result in illegal actions, such as lying to an inspector or falsifying or destroying records.

A. The Arrival of the Inspector

1. Responsibilities of the Employee Who Greets the Inspector

The receptionist or other person who typically greets visitors must know what to do when the inspector arrives.

- ☐ Be sure that the inspector is escorted at all times.
- ☐ Know which employee has been designated as the Company Contact and which employees have been designated as the Alternate Company Contacts.
- ☐ During normal office hours: Notify the Company Contact/Alternate Company Contact that the inspector has arrived.
- ☐ Other than normal office hours: Make every effort to have him or her return during normal office hours. If the inspector insists on performing the inspection, advise him that he will have to wait for the Company Contact and notify the Company Contact. If the inspector continues to insist on inspecting and there are ongoing operations, consult with company management and counsel.

2. Responsibilities of the Company Contact

- ☐ Examine the inspector's credentials; diplomatically confirm that he or she is, in fact, a food inspector.
- ☐ Ensure that the Support Team is notified that a food inspector has arrived and is also informed of subsequent developments.
- ☐ Ensure that all working areas are prepared for an inspection and that all appropriate employees make themselves available for consultation with the Company Contact.

- ☐ Try to delay the inspection for a reasonable period of time if necessary for the Inspection Team to assemble and prepare.

B. The Opening Conference

The formal part of the inspection begins with an opening conference. The opening conference is used by the inspector to inform the company as to the purpose and scope of the inspection and what it will involve. It can set the tone of the whole inspection and should be considered a very important part of the inspection process.

From the company's viewpoint, it is critical to learn, to the extent possible, why the inspector is there and what the inspector plans to do. The FDA Investigations Operations Manual directs the inspector to outline in general terms the scope of the inspection, including the physical inspection of the operations, records review, any complaints received, and the nature and purpose of the closing conference. If the Company Contact does not feel the inspector has been sufficiently informative, he or she should not hesitate to ask for additional details. The Company Contact should handle all conversations with the inspector.

FDA inspectors are required to present the Company Contact with a formal Notice of Inspection (Form FDA-482, shown in Appendix A or Form FDA-482(c), shown in Appendix D), before they are authorized to continue the inspection. This is a printed form with spaces to be filled in, showing the date, the name and title of the responsible member of the firm to whom the notice is being issued, the firm name, and location of the plant. The Notice of Inspection also quotes the language from the FD&C Act which grants FDA its inspection authority. It should be signed by the inspector and should bear the name and address of the District Office from which he or she operates. This notice should be kept on file for later reference. Some state or local officials may not present this notice; in such cases, the Company Contact should write down all pertinent information provided regarding his or her inspection authority.

From the company's viewpoint, it is critical to learn, to the extent possible, why the inspector is there and what the inspector plans to do.

WORKSHEET: OPENING CONFERENCE

Date of Inspection:

Time of Opening Conference:

Name of Recorder:

Name of Company Contact:

Name of inspector:

Names of anyone else present:

What records has the inspector asked to review?

What physical parts of the plant has the inspector asked to inspect?

What, if any, complaints has the inspector asked about?

On what points, if any, did the Company Contact ask for further clarification?

Notice of Inspection (Form FDA-482 or Form FDA-482(c)):

- Was it presented to the Company Inspection Team?
- Are all spaces filled in, including the date, name/title of person at the company to whom the notice is issued, the company name, and the plant location?
- Is it signed by the inspector?
- Does it include the name and address of the inspector's District Office?

If a state or local official does not present a Form FDA-482 or Form FDA-482(c), record the relevant information regarding the official's inspection authority:

C. Inspection Procedures and Assertion of Your Legal Rights

As stated earlier, the Inspection Team and Company Contact are responsible for protecting a company's right to maintain the secrecy of its trade secrets and other confidential information, and possibly other rights. To review, the policies you should have established regarding inspection procedures cover:

- Escorting the inspector at all times
- Who responds to questions and requests
- Disclosure of information, documents, and other records
- Affidavits and Similar Documents
- Sound Recording Equipment
- Photographic Equipment
- Inspector's Compliance with the Company's Health and Safety Rules
- Sampling

I. Interacting with the Inspector during the Inspection

When accompanying the inspector, the Inspection Team should be courteous and respectful, while at the same time firmly standing up for the company's rights and viewpoints. The Inspection team should keep the following points in mind.

- ☐ The company should act promptly on any valid suggestions made by the inspector that are clearly related to food safety, either at the time of the inspection or shortly thereafter. But this does not require the company to provide the inspector with information that might be used to form the basis for a citation. Be certain to point out any misinterpretations on the part of the inspector, during the visit, that resulted in unwarranted safety concerns.
- ☐ Remember that the inspector may provide useful advice but is primarily there to review regulatory compliance. Therefore, the Company Contact must exercise caution in disclosing information, and must not let an inspector make the Company Contact feel defensive about following company policy or exercising legal rights.
- ☐ Do not admit any violations of any laws or regulations. Furthermore, avoid making any statement which could be construed as an admission of a violation.
- ☐ Under no circumstances should the Inspection Team give false or misleading information. If you are not sure of the answer to a question, say "I don't know."
- ☐ Do not volunteer information to impress the inspector with your knowledge. Restrict your conversation to matters covered by the inspection.
- ☐ Do not initiate discussion of an incident or complaint which involved the products of the company or its competitors. Use discretion in responding to the inspector's questions regarding such incidents or complaints. Generally, you should provide sufficient information to demonstrate to the inspector that there never was a health hazard or that there is no continuing hazard (if accurate) and that the company is dedicated to food safety and quality, without providing any evidence which would indicate possible violations.

Accompanying an inspector can be a significant undertaking. For this reason, it is generally recommended that two employees accompany each inspector: one to answer questions, and the other to carefully note all activities.

2. Take Detailed Notes on the Inspection

Accompanying an inspector can be a significant undertaking. For this reason, it is generally recommended that two employees accompany each inspector: one to answer questions, and the other to carefully note all activities.

The member of the Inspection Team who is not the Company Contact should carefully observe and note all activities of the inspector—including discussions, areas visited, sampling, records inspection, etc. Any notes taken by employees may later be used in legal proceedings. Therefore, it is important that the notes do not contain any statements which you would not want to be seen by people outside the company.

3. Immediate "Correction" of Alleged Violations Noted by the Inspector

During the inspection, the inspector may point out conditions which he or she considers to be in violation of the FD&C Act or other applicable law. In appropriate situations, the Company Contact could direct firm employees to modify or begin modification of those conditions. Factors to be considered in making this determination are:

- ☐ The potential hazard presented by the condition
- ☐ The likelihood that the condition noted does constitute a violation of the law
- ☐ Whether the modification can be accomplished without undue interference with normal operations

WORKSHEET: DURING THE INSPECTION

Date of Inspection:

Time of Inspection:

Name of Recorder:

Name of Company Contact:

Name of inspector:

Names of anyone else present:

What areas of the plant did the inspector inspect?

What records did the inspector review?

What samples did the inspector take (be sure to get a Form FD-484 for each sample)?

What else was discussed during the inspection?

What, if any, modifications were made immediately in response to the inspector's comments

D. Closing Conference

After completing the walk-around phase of the inspection, the inspector will conduct a closing conference with the Company Contact. At least one other company employee designated by the Company Contact should attend the conference and take detailed notes of the discussion. The inspector will review:

- The conditions and practices which he or she believes could be improved
- Conditions and practices which he or she deems to be citable violations
- Applicable sections of the regulations which he or she feels have been violated
- Consumer complaints received by FDA, to obtain an explanation for the condition cited and to determine what corrective action, if any, has been taken

Any consumer complaints may also be referenced during the Opening Conference. If asked about consumer complaints, carefully discuss the condition complained of using the following approach:

- If the company has not received a similar complaint, so advise the inspector.
- Point out all reasonable explanations for the condition which might involve an event for which the company would not be responsible (for example, improper storage by retailer).

1. Formal Notice of Possible Violations

Prior to leaving the premises, an FDA inspector may furnish the Company Contact with a Form FDA-483, (shown in Appendix E), listing the objectionable conditions or practices observed. State and local food inspectors may leave a checklist type form listing such conditions.

The Company Contact should review the FDA-483 or state form and clarify any differences of opinion. The Company Contact should not engage in a debate with the inspector regarding the observations. On the other hand, the Company Contact should be alert and advocate the company's position.

2. Abatement of Conditions Noted As Possible Violations

If any conditions noted in the FDA-483 have been modified in the presence of the inspector or before he or she leaves, ask the inspector to include that fact on an "annotated 483" or in the inspection report. If it was not possible to modify these conditions before the inspector left, they should be modified as quickly as possible.

The Inspection Team should subsequently draft a written response to the FDA-483, have it reviewed by Management and counsel, and send it to FDA within 15 business days to ensure that it will be considered before FDA decides whether to issue a Warning Letter. Depending on the state, written responses may also be sent to state inspections.

3. FDA Reports

In addition to the FDA-483, an FDA inspector will also prepare, for internal FDA use, an Establishment Inspection Report (EIR). This is usually a detailed report of all aspects of the inspection, the answers to all questions, a summary of all observations—favorable as well as unfavorable—and a recital of company responses to the inspector's adverse observations.

Following an inspection, FDA will provide a copy of the EIR to the inspected firm, assuming FDA is not planning to take follow-up regulatory action. At the closing conference, the Company Contact should confirm with the inspector that a copy of the EIR will be provided to the firm without the need to make a Freedom of Information Act request.

But unless FDA is considering or has initiated enforcement action, all documents prepared by FDA in connection with the inspection, other than confidential business information, are available to the

public through a Freedom of Information Act (FOIA) request. Regarding confidential information, FDA will consider a company's designation of information as confidential, but FDA makes the final determination. And there is always the possibility that FDA may mistakenly disclose confidential information in answering a FOIA request. Thus, it is recommended that FDA be given both a full copy and a redacted copy of a document containing information that the company considers to be confidential. If FDA agrees with the company, the redacted copy can be provided in response to a FOIA request.

4. Internal Company Report

The Company Contact, with the assistance of the other members of the Inspection Team, should prepare a complete report on the inspection shortly after the inspection. Copies of this report should be marked "CONFIDENTIAL" and distributed to appropriate firm personnel, including counsel.

WORKSHEET: CLOSING CONFERENCE

Date of Inspection:

Time of Closing Conference:

Name of Recorder:

Name of Company Contact:

Name of inspector:

Names of anyone else present:

What, if any, conditions or practices did the inspector note for improvement?

What, if any, conditions or practices did the inspector deem to be in violation?

What, if any, sections of the regulations did the inspector deem to be violated?

What, if any, consumer complaints did the inspector reference?

How did the Company Contact respond to the consumer complaint(s) referenced?

If the inspector furnished a Form FDA-483, how did the Company Contact respond?

If any modifications were made immediately in response to the inspector's comments, was an annotated 483 provided?

Who will draft a written response to the FDA-483? By when?

Did the Company Contact confirm with the inspector that a copy of the Establishment Inspection Report will be provided to the firm without the need to make a Freedom of Information Act request?

Who will draft an internal company report? By when?

IV. APPENDICES

APPENDIX A: Notice of Inspection Form FDA 482

APPENDIX B: Demand for Records Form FDA 482A

APPENDIX C: Request for Information Form FDA 482B

APPENDIX D: Notice of Inspection - Request for Records Form FDA 482C

APPENDIX E: Inspectional Observations Form FDA 483

APPENDIX F: Receipt of Samples Form FDA 484

15525 Sand Canyon | Irvine, CA 92618
949.863.1000 | Fax 949.863.9028 | www.wga.com

Prepared for Western Growers by:
Leslie T. Krasny, Esq.
Keller and Heckman LLP

Three Embarcadero Center, Suite 1420
San Francisco, CA 94111
(415) 948-2800 | www.khlaw.com