GUIDE[1] TO PRODUCE FARM INVESTIGATIONS

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INTRODUCTION

Over the last several years, there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables. These outbreaks have raised concern for the safety of fresh fruits and vegetables that are not processed to reduce or eliminate pathogens.

There are two primary reasons for conducting a farm investigation: 1) an outbreak and trace back investigation that implicated the farm and related operations and 2) follow-up to a positive produce sample. Prior to implicating the farming operation, all other possible sources of contamination in the distribution chain should have been fully investigated.

Farm investigations are just one aspect of FDA's produce safety efforts, which also include domestic and international education and outreach in Good Agricultural Practices (GAPs). These efforts are intended to improve agricultural practices to reduce risks of microbial contamination of fresh fruits and vegetables. These ongoing efforts involve cooperation and collaboration with industry and trade associations, academia, and other government agencies.

OBJECTIVES

- Minimize the potential for illness caused by produce that is grown, harvested, packed, and transported under unsanitary conditions from entering interstate commerce.
- Document possible sources of microbial contamination that may have led to the produce associated outbreak or positive sample.
- Provide a basis for placing or lifting an import alert on imported products.
- Build a scientific base to assess the relative microbial risk of on-farm practices.
- Refine Agency policy and guidance aimed at reducing foodborne illness related to fresh produce.

This Guide provides detailed procedures that will better enable FDA to reach its goals in this type of investigation.

PURPOSE

The purpose of a farm investigation is to gather information, and observe and document practices that may have led to the pathogen specific contamination of produce, and that will support regulatory action if appropriate. Information is gathered using both traditional fact finding techniques and the FDA Farm Investigation Questionnaire.

LEGAL BASIS

Investigators should be aware that there is an exclusion for raw agricultural commodities in 21 CFR 110-Current GMP's for Food, under section 110.19. This section states that: (a) "Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public" are not subject to 21 CFR Part 110. In the preamble to the final rule (51 FR 22464), FDA advised that because

these regulations were concerned specifically with the manufacturing, packing, and holding of foods, it was not reasonable to apply them to raw agricultural commodities. FDA also stated that raw agricultural commodities, as defined by 201(r) of the Act, will continue to be regulated simply under the adulteration provision of the Act (Section 402) and not under the GMP regulations.

FDA has issued Guidance for Industry 'Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (GAP Guide). This guide identifies the broad microbial hazards in the production of fresh produce, and provides FDA recommended good agricultural and management practices for reducing the risk of microbial contamination; but this document is guidance only, and is not enforceable.

Farming operations, and subsequent operations in packing sheds and buildings, may not meet all requirements outlined in 21CFR110 or recommendations in the GAP guide. However these documents serve as a useful tool in assessing whether raw agricultural products are handled under conditions that may adulterate the food. Bear in mind that produce is typically eaten raw and there's no thermal treatment to reduce pathogen levels.

INVESTIGATION TEAM

TEAM SELECTION

A farm investigation should be conducted by a multi-disciplinary team at the implicated farm(s). The investigation may be domestic and/or international. An FDA ORA Investigator will lead the team unless other arrangements have been made for the investigation to be conducted by other agencies/organizations. The team may include individuals from The Center for Food Safety and Applied Nutrition (CFSAN) and Office of Crisis Management/Office of Emergency Operations, (OCM/OEO), Mail Stop HFA-615, PH 301-443-1240; and other federal agencies [i.e., Center for Disease Control (CDC), U.S Department of Agriculture (USDA), Environmental Protection Agency (EPA)], or state/local agencies. It should include an investigator with a food inspection background, a microbiologist, an epidemiologist, a water systems expert/sanitarian, and possibly an agronomist. It is helpful to have an epidemiologist that is also a physician or veterinarian (if animals are the suspected source of the outbreak) on these investigations. The expertise needed will depend upon the nature of the outbreaks, the type of pathogen and product that is under investigation, and the location of the firm. Some team members may serve as the expert for more than one subject area. Typically, an epidemiologist, microbiologist, and water expert have served as team members with the lead being an ORA Investigator. At least one person on the team should have completed the FDA Produce Farm Investigation training course.

Domestic Investigations

Either OCM/OEO or Division of Field Investigations (DFI), Mailstop-HFC-130, PH 301-827-5653, may issue assignments for farm investigations. The district will identify and assign an experienced FDA investigator to lead this type of investigation. In addition, the district may provide other team members, such as a microbiologist. The intention is to use the home district's personnel first if they have the expertise, and then identify other individuals with additional expertise that is needed to complete the team. OCM/OEO and DFI will work with CFSAN Emergency Coordination and Response Staff (ECRS)/Office of Compliance (OC), to ensure that the team has the appropriate expertise.

Foreign Investigations

If a foreign firm is implicated, then OCM/OEO will notify DFI when the traceback is complete. OCM/OEO will provide DFI with a list of the particular skills that are desired of the team members for a foreign farm investigation. Upon request from DFI, districts should submit a list of their nominees and their specific skills and qualifications, for consideration. OCM/OEO will work with CFSAN to identify individuals outside of ORA that may be needed to complete the team.

ROLES AND RESPONSIBILITIES

The roles and responsibilities of team members should be clearly defined and discussed prior to the farm investigation. This is critical to the success of the investigation and maintaining positive relations with other government officials. This discussion should involve OCM/OEO and CFSAN. The role of the lead investigator and interaction among the team members is outlined in the Investigations Operations Manual (IOM), Section 5.1.2.5 - Team Investigations. All team members should review this IOM section. Additional and specific responsibilities are listed below:

Lead Investigator:

- Refer to IOM 5.1.2.5
- Develop a trip itinerary and ensure that all team members have submitted travel documents.
- Coordinate with the District and OCM/OEO a pre-trip and post-trip conference call.
- Time reporting for all of the FDA investigators, and handling all contact with domestic firms and local government agencies.

Epidemiologist:

- Identify to the lead investigator information and coordination needs regarding worker health and hygiene practices.

- Identify potential public health agencies to be interviewed for the worker health and hygiene aspect of the investigation.
- Interview the public health authorities, farm employees, and farm management regarding worker health and hygiene practices and disease prevalence in the area.
- Complete the Worker Health and Hygiene section of the Farm Investigation Questionnaire and provide the narrative for this section in the EIR.

Microbiologist:

- Prior to the farm investigation, provide team members with background information on the typical reservoir and products that the pathogen has been associated with. Provide the conditions of survival and potential for growth of the pathogen involved. This may be verbal information shared during conference calls.
- Identify microbial sampling equipment needs and draft a sampling plan, as applicable. In coordination with the lead investigator, identify a laboratory and arrange shipment of supplies to the investigation site; and once collected, arrange shipment of samples to laboratories for analysis.
- Guide the team on microbial risks of farm practices and contamination sources during the investigation, such as opportunities for survival and multiplication of the pathogen of concern.
- Jointly with the ORA Investigator collect and ship samples to the laboratory.

Environmental Sanitarian/water expert:

- Prior to the on-site farm investigation, provide the lead investigator with a list of information (water facility info, well diagrams) and equipment needs that pertain to environmental sampling and testing. Examples of field equipment include appropriate testing equipment for water quality, e.g., chlorine or iodine test strips, pH paper etc.
- Perform and record appropriate non-microbial water tests during the on-site investigation.
- Assess well integrity, and water disinfection/treatment systems.
- Identify possible cross-connections and other sources of contamination of water used.
- Interview appropriate parties to obtain water quality and aquifer data.
- Assist team with recommendations for environmental sampling, as applicable.
- Complete the Water Sources section of the Farm Investigation Questionnaire and associated forms from International Association For Food Protection (IAFP) handbook "Procedures to Investigate Waterborne Illness", 2nd Edition 1996- See Attachments 5-11.

While on-site each team member is responsible for identifying areas of concern, and if possible, communicating the information to other team members at the time of observance. This helps in prioritizing and assessing significance to observations as well as identifying possible sampling sites. All team members are expected to contribute to the final report, including write-up of sections in their area of expertise.

PLANNING & COORDINATION

For a domestic investigation OCM/OEO or DFI may issue assignments for farm investigations. The issuing office will issue an assignment in FACTS to the appropriate district. Occasionally districts may be requested by their state counterparts to initiate investigations. In those cases the District should inform OCM/OEO and DFI, and issue the assignment in FACTS. Since FDA typically does not investigate farms, an FEI may not exist. If one doesn't exist, follow the procedures for generating an FEI in FACTs and mark the workload obligation 'yes'. For foreign investigations DFI/ International Operations Group (IOG) will issue a FACTS assignment.

Pre-trip conference calls will be arranged by the lead investigator as soon as s/he is notified of the farm investigation and selected as Lead. The team will be briefed by CFSAN and OCM/OEO on all aspects of the outbreak investigation, including the epidemiological, environmental, and laboratory findings, and the traceback results. The team members' roles and responsibilities will be discussed. Other items that will be discussed include travel, contacting the firm(s), shipment of supplies, communication, equipment needs, on-site logistics, samples, and laboratory analysis.

The FDA team members should review the following for guidance prior to the investigation:

- Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food (21 CFR 110)
- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables (GAP Guide), and Guide at a Glance, both available at: http://www.foodsafety.gov/~dms/fs-toc.html#prod
- IOM Chapters 5 & 9 available at: http://www.fda.gov/ora/inspect_ref/iom/
- Farm Investigation Questionnaire, Form FDA 3623, available at http://www.fda.gov/opacom/morechoices/fdaforms/ora.html
- Procedures to Investigate Waterborne Illness, 2nd Edition, IAMFES
- Procedures to Investigate Foodborne Illness, 5th Edition, IAMFES, both available for purchase at: http://www.foodprotection.org

Note: Investigators should be familiar with the exclusions to 21 CFR 110 regulations cited under 21

CFR 110.19. See 'Legal Basis' section of this inspection guide.

COORDINATION

For domestic investigations, the Lead investigator will contact the firm to determine whatever preliminary information is available regarding the location of implicated fields and/or related packing operations based on shipment dates and traceback information. Contact the state agricultural and/or health authority to notify them of your investigation. You are encouraged to invite a state representative to come as an observer. Depending on the state's experience, they may be an active participant of the investigation. Leverage your resources as much as possible.

For foreign investigations, the Office of International Programs (OIP) will make the initial contact with the foreign government to obtain this information from the firm. Thereafter, the Lead investigator will work through the foreign government officials for coordination and information gathering.

LOGISTICS/TRAVEL

To make most efficient use of time, estimate the duration of the investigation and determine travel distances between investigation sites. Map out the locations that are to be investigated based on the location of the suspect fields and packing facility, and in relation to the team's accommodations. The packing facility and fields may be significant distances apart and/or the terrain may be difficult. The local contact in the area often provides very useful information and guidance on the challenges of the geographic location. Consult the local authority early in the planning process. You may be able to obtain more detailed maps from the local authority.

- Contact DFI for foreign travel arrangements for ORA. OCM/OEO and CFSAN are responsible for foreign travel arrangements for their team members. A Notification of Foreign Travel (NFT) must be submitted as soon as possible for all team members even if based on preliminary information, as 37 days advance notice of foreign travel is required by the Foreign Travel Guidelines (although some exceptions are made for regulatory travel of an emergency nature).
- Request OCM/OEO to contact OIP for: initial contact with the foreign government; to request an interpreter be provided if no team members are fluent in the appropriate foreign language; to identify a contact in the U.S. Embassy, particularly the Foreign Agricultural Attaché for the country you will be traveling; and in-country contacts for foreign agriculture and health officials. The Lead investigator should communicate with the embassy contact to make arrangements for shipping of supplies into the country and shipping samples back to the U.S., or within the foreign country. The Agricultural Attachés have insight into the political nature of the country and any consequences your inspection might have on the economic sector of the industry being inspected.
- Provide each team member's flight information and draft itinerary to OIP.
- Consider any special needs of team members in the planning of the trip since you may be in a remote area.
- Refer to the "Guide to International Inspection and Travel" which is on the DFI/ FDA Intranet site.

EQUIPMENT

A list of potential field equipment including that needed for sampling is listed in Attachment 1. Modify the list to satisfy the investigational needs. Attachment 1 also lists a Center contact for obtaining a field kit, which will include two global positioning satellite units (GPS), walkie-talkies, and other investigational supplies. The GPS is for quantifying distances of contamination sources to the field. Other supplies needed include flashlights for examining the inside of hydrocoolers for animal feces, sterile wide-mouth sample bottles for water collections, large whirlpak bags (or if unavailable, new unopened garbage bags) for collecting large subsamples, and total and free chlorine test strips in various ranges for measuring process water and/or hand sanitizers. The lead investigator and microbiologist will obtain the supplies from the ORA laboratories designated by DFS, and give the analyzing laboratory advance notice of the approximate number and types of samples to be collected, and microbes to be analyzed for.

Reference materials should also be brought with the team. This includes, but is not limited to the IOM, 21 CFR Part 110, The Federal Food, Drug and Cosmetic Act, the GAP Guide, this Guide, Farm Investigation Questionnaire, Procedures to Investigate Foodborne (or Waterborne) Illness, and inspectional forms 483's and 484's. The reference section at the end of this guide identifies websites for references.

SAMPLING AND TESTING

The focus of the investigation should be observations and fact finding. Sampling should not be the single significant tool in an investigation unless it will help establish the source of the contamination. As the investigation progresses the team will prioritize and determine if sampling is appropriate, and exactly where and what to sample. The lead investigator secures the FACTS sample numbers.

For foreign investigations some testing may need to be arranged in-country. Limit this to samples not intended to support regulatory action, unless a full analytical package can be submitted. Significant planning prior to the on-site investigation is needed for this to be successful. Issues to be addressed in

determining whether to utilize a foreign government lab are: the level of confidence in the analysis based on the quality system and methods used; availability of the laboratory; commitment to the number and type of samples; payment of service issues; and agreement to report results to FDA. Water testing for bacterial indicators is one type of analysis that has a limited holding period (24 hrs) prior to analysis that is easily exceeded when one attempts to ship samples back to the US.

For samples that will be analyzed by FDA it is highly recommended to contact the U.S Embassy, Foreign Agricultural Attaché, in the foreign country to request their assistance in shipping samples back to the US. Not only does this facilitate shipment but it also enhances chain-of-custody of the samples. You may also need to alert Customs to your shipments to minimize any delays.

In addition, Prior Notice (PN) requirements established as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), require prior notification for shipments of food samples entering the United States. Note however, enforcement discretion for laboratory samples may be exercised in the near future which will negate the need for filing PN in these circumstances. You should contact the Prior Notice Center (PNC) at the number noted below to determine the current policy, prior to shipping food samples. Non-food samples, e.g., processing water samples, do not require PN, but the package should be clearly marked as containing a non-food laboratory sample.

Unless/until the enforcement policy is changed food samples by regular mail will require a prior notice confirmation number be annotated on the outside of the package, and express couriers will require a prior notice confirmation number be provided to them at or before package pick up. The prior notice confirmation number can be obtained by entering required prior notice information in the FDA Prior Notice System Interface (PNSI) system at www.access.fda.gov. In order to make this process easier, FDA employees traveling abroad may contact the PNC for assistance. The PNC is open 24 hours a day, seven days a week, and can be contacted at 866-521-2297 or (703) 621-7732. You should identify yourself as an FDA employee (for verification in Outlook) traveling abroad on assignment, and needing assistance in filing a PN for a food sample, or you can request the PNC employee file a PN for you. You should be prepared to provide details about the product/shipment including: product name and quantity, manufacturer name and address, lab name and address etc. This may take 30 minutes to complete by phone. Once the PN is filed and the confirmation number is obtained the food shipment may be shipped following all other international procedures, and should proceed for delivery in the United States without unnecessary delay.

CONDUCTING THE INVESTIGATION

- Focus the team's investigation on the time period and conditions that existed during the growing, harvesting, packing, and cooling of the product implicated in the outbreak or positive sample.
- Use the team's expertise to investigate and evaluate sources of microbial contamination based on the pathogen of concern. If the pathogen's only reservoir is humans then focus on disease prevalence in the community and farm work force, worker hygiene, and contaminated water and sewage inputs. This would apply to pathogens such as Shigella bacteria, Hepatitis A virus, Norwalk-like virus, and the parasite Cyclospora. If the pathogen of concern has both a human and animal reservoir then the investigation will be broader to cover possible animal contamination sources. These bacterial pathogens include, but are not limited to Salmonella and Escherichia coli 0157:H7.
- Consider any cultural considerations and protocols that should be followed.
- Use your investigative skills, the GAP Guide, and the Farm Investigation Questionnaire as the foundation of the investigation. It is suggested that you insert the Questionnaire in a 3 ring binder.

Additional agencies that need to be visited during the investigation should have been identified prior to the on-site investigation. These typically include local public health agencies or clinics, the water commission, and possibly a laboratory used by the firm. For a domestic farm investigation it may be possible to obtain the necessary information by phone or mail, rather than on-site. However, for a foreign investigation you should conduct personal interviews if possible. Incorporate sufficient time to accomplish this.

ON-SITE

- Follow the general principles outlined in chapter 5 of the IOM, including section 5.4.7-Sanitation.
- Plan a team meeting prior to meeting with government officials or the firm to have a final strategy/planning session.
- Arrange a meeting with any local, state or foreign officials prior to meeting with the firm. Provide an overview of the outbreak, traceback and purpose of the farm investigation.
- Meet with the responsible party at the firm, show credentials, issue an FDA- 482, Notice of Inspection (for domestic inspections) and explain the reason and purpose for the investigation. Request an overview of their production areas and farming operation from planting to packing.

- Maintain communication with the home district and OCM/OEO during the investigation. DFI and OCM/OEO will be the contact for guidance on foreign investigations. OCM/OEO will contact CFSAN Emergency Coordination and Response Staff (ECRS) if scientific and policy guidance is requested.

The subsections below are arranged according to the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables."

Farm Investigation Questionnaire

The Farm Investigation Questionnaire, is for gathering specific information related to conditions that may have lead to product contamination during the time period of interest. It covers Good Agricultural Practices. Fillable Adobe versions of the Questionnaire (Form FDA 3623), and additional Water Source Section (Form FDA 3623a) and Worker Health and Hygiene section (Form FDA 3623b) are available at http://www.fda.gov/opacom/morechoices/fdaforms/ora.html

Each team member should complete his/her predetermined sections of the Questionnaire. The information contained in the completed Questionnaire will be part of the EIR, either as an attachment or in the narrative body of the EIR.

DIAGRAMS/LAYOUTS

Diagramming the farm layout and its surroundings will assist in identifying and assessing contamination sources. If the firm can't supply a diagram, sketch one with the firm's assistance. This should be specific to the implicated fields, surrounding area, and packing facility. Be sure to include potential sources of contamination (e.g., cattle feed lot) and topography (slope for run-off and barriers). Diagram the process flow of the product from field to packing. Draw a schematic of the packing facility operation. Refer to the water section of this guide for other diagrams to be completed.

WATER

Determining water quality and sources is a critical part of the investigation. Water sources may be surface (rivers, ditches, and lagoons), or ground water (wells, springs). Water quality should be determined for the growing, harvesting, cooling, and packing operations. Water provides a means for spreading contamination to and among product. Fill out the water source portion of the Questionnaire, and complete the appropriate forms from Procedures to Investigate Waterborne Illness, 2nd edition 1996 (See Attachments 5-11). If more than one source of water is used, complete additional water source form, FDA 2623a, for each water source (e.g. sources for growing, packing, processing and transportation).

Agricultural water

- Determine the source and quality of water used for irrigation, to mix fertilizer and pesticides, and for any field washing and rinsing.
- Obtain documents that would indicate the water quality, particularly microbial, and its intended use.
- Review existing uses and conditions of the water system to identify potential sources of contamination.
- For ground water, determine whether the well is protected from surface contamination and obtain data to show that the well is properly constructed.

Agricultural water can become contaminated directly or indirectly, from human or animal waste. Human contamination may come from untreated sewage, improperly designed or malfunctioning septic systems, and combined sewer overflows. Examples of on-site sources of contamination from animal waste are animal pasturing in or near the growing area; run-off from manure or leachate stored adjacent to crop; livestock or wild animals with access to surface waters, wells, or pump areas; or habitation in or near the water sources by animals or humans. Document evidence with pictures of human or animal feces and correlate the distance to water source or field.

There is no microbiological standard for agricultural water. Total coliform bacteria are not typically used to characterize irrigation water. Fecal coliform, E.coli, or Enterococci are better microbial indicators for irrigation water quality. Pathogen testing is also useful.

For irrigation, the method of irrigation aids in assessing the microbial risk associated with water usage. The greater the contact with the edible portions of the fruit or vegetable the greater the microbial risk of contamination if the water quality is inadequate. Drip or furrow irrigation tends to be of lower risk than overhead spray.

The shorter the duration is between application and harvest the greater the likelihood of pathogen survival. Pesticides may be applied close to harvest so it is important to determine the source and quality of water used to mix pesticides. Document application dates and crop type correlated to the time period of interest.

Process water

Processing water should be of such quality that it does not contaminate the produce. Water used in processing, particularly a final rinse of produce, should be drinking quality water (non-detectable total coliform bacteria per 100 milliliters per EPA standard 40 CFR 141-National Primary Drinking Water Regulations available at: http://www.access.gpo.gov/nara/cfr/waisidx_02/40cfr141_02.html) Potential water uses include dump tank,

flume transport, wash or cooling, and possibly waxing. Hydrocoolers and dump or immersion tanks may allow build-up of soil, organic materials, and microbial loads, including pathogens.

- Determine the source of the water and frequency of changing the water.
- If a municipal water source is used, does the firm obtain water quality information from the water authority? Were there any failures in treatment during the period in question?
- Determine if disinfectants are used and if levels are monitored and maintained throughout the process. Test the temperature, disinfectant concentration, and pH of the process water while on-site. Some operations monitor oxidation reduction potential (ORP) to control disinfectant levels. ORP is a measurement in millivolts of disinfection concentration and pH (see Reference section, item 8 for technical resource).
- Determine whether the person monitoring the levels knows when to add disinfectant based on values obtained.
- Determine if monitoring equipment is adequately maintained and periodically calibrated.
- Review records and document disinfectant levels of all process water that came in contact with workers or product for the time period of interest. Repeat for current operation.
- Is the water periodically tested? If so report on analytical results.
- Depending on the observations, this may be a good sampling location.

Water may be continuously reused or recycled. Water quality is especially important at the end of the process when sequential processing is used. Water should be of sufficient quality for its intended use throughout all processes.

MANURE/BIOSOLIDS

Manure and biosolids may be used in soil preparation and as fertilizer. Synthetic fertilizers are common but soil amendment or side dressing may be used, and may contain untreated or improperly treated manure. Animal manure and human fecal matter represent a significant source of human pathogens. E. coli O157:H7 and Salmonella are common inhabitants of certain animals. Consequently, improperly treated manure or biosolids can be a source of microbial contamination.

- Obtain information on manure source, treatment, storage on-site, and timing of applications. Raw manure represents a high risk of microbial contamination and is not recommended.
- Examine whether run-off from manure storage and treatment areas could contaminate the crop.

Animal management and wildlife are a concern based on animal waste contaminating produce both in the field and packing facility.

- Document the number and types of animals, and their feces, the distance from the crop or water sources, and topography. Bear in mind that there may be nocturnal animals and/or animals that only feed on fruit during cooler parts of the day. Workers and their families living on the edge of the field(s) are an excellent source of information.

WORKER HEALTH AND HYGIENE

The importance of workers and supervisors understanding and practicing proper hygiene cannot be overemphasized. Workers can contaminate fresh produce, water supplies, and other workers, and transmit foodborne illness if they do not understand and follow basic hygienic principles. During this part of the investigation cover community disease surveillance, worker health and hygienic practices, and the firm's training program for worker health and hygiene. Fill out the worker health and hygiene section of the Questionnaire for each set of workers based on worker type (field or packing facility worker) and location. Form FDA 3623b is for reporting on additional sets of workers.

Information obtained on worker health typically involves the local community and public health official in the area of farming operations. Information should be gathered on disease surveillance and any outbreak in the community during the time period that the implicated product was harvested and packed. Contact and interview the local health authority on-site. Determine if there are health services for migrant workers. Often individuals will not seek medical attention for diarrheal disease; the local clinic may not have the ability to collect clinical samples; or surveillance is not specific to illness (listing diarrheal illness instead of Salmonellosis). Document these conditions.

Contributing factors to workers and their families' health and hygienic practices include poor living conditions, lack of safe drinking water, and lack of, or inadequate sanitary or hand washing facilities.

- Identify steps from harvesting to packing and transport, where workers handle the produce or come in contact with materials or water that also comes in contact with the produce.
- Observe and record the practice and frequency of hand washing in field and packing facility.
- Determine if children accompany workers in the field or packing facility and whether diapers are used, and method of disposal. Fecal material is a potential contamination source for workers and water.
- Determine training frequency and whether training covers workers health and hygiene. This

information indicates the level of attention given by the responsible parties for health and hygiene of workers.
- Interview employees to determine if any that had contact with produce were ill during the time in question. Check employee absentee records.
- Determine if the field workers speak the language that is used for training
- Determine water source for hand washing and drinking, and if hand sanitizing solutions are used. Determine whether hand rinse waste water is collected, or allowed to drain into fields or in the vicinity of packing operation.

SANITARY FACILITIES

This section covers toilet and hand wash facilities and waste/sewage disposal for both the field and packing facility. Operations with poor management of human and other wastes in the field or packing facility can significantly increase the risk of contaminating produce. The lack of sanitary facilities, and inadequately supplied or improperly maintained restrooms and hand washing facilities may provide direct or indirect contamination of the crop and water sources used on the crop.

- Record the availability, number, and location of sanitary facilities in relation to the number of workers and their work location, and whether workers appear to be using the facilities.
- Inspect the condition of the restrooms and cleaning schedule.
- Determine the cleaning and disposal location of sanitary waste including holding tanks and portable toilets.
- View and document the condition of the waste disposal site if on-location, and maintenance records.
- Visually inspect access manholes if there is likelihood of overflow draining into the field; record any obstructions.
- Check for cross connections and if back flow prevention devices are used when necessary.

If improper collection or drainage of flush toilets is suspected, consider using florescent dye tablets to follow the flow of waste to identify any system failures.

FIELD SANITATION

Microbial contamination or cross-contamination of fresh produce during pre-harvest and harvest activities may result from contact with soils, fertilizers, water, workers, and harvesting equipment. Any of these may be a source of pathogenic microorganisms.

- Examine the condition and use of the harvest tools, containers such as sacks and bins, crates, and pallets, and farm machinery.
- Examine tools and equipment for evidence of animal fecal material and soil accumulation.
- Look for items or areas that would attract animals, like tall grassy areas, standing water, trash/debris accumulation, or produce refuse.
- Record sanitation practices for cleaning equipment to minimize the potential for contamination of the produce, including pesticide and fertilizer equipment. Examples of items to cover include frequency of cleaning, source of cleaning water, concentration of sanitizer, and frequency of changing batch water or dumping recycled water.
- Determine where and how harvest tools and containers are stored when not in use, in-season and off-season.
- Determine who has control over the equipment including harvest tools.

PROCESSING/PACKING

Packing may occur in the field or packing facility. Examine the sanitary conditions under which the produce is packed and identify possible sources of microbial contamination. Some areas to cover include: wildlife or domestic animal harborage; quality of water used for rinsing, and disinfectant levels; cleaning and sanitizing of equipment; the condition and storage of packing materials, and product storage. Consider nocturnal animal activity (opossum, iguana). Look for birds roosting in packing facilities above conveyors and packing equipment. Determine the degree of hand contact in sorting, grading, and packing. Observe the operation, including employees returning to their workstations after taking breaks.

Use the GMP's as an inspection tool. Your investigation should concentrate on examining sources of microbial contamination specific to the pathogen in the outbreak and the conditions during the time period in question. For example, observation of peeling paint does not relate to Shigella contamination.

- Verify cleaning and sanitation schedules and the firm's pest control program.
- Look for items or areas that would attract animals, such as tall grassy areas, standing water, trash/debris accumulation, or produce refuse.
- Inspect surrounding grounds for pest problems, inspect equipment (inside and out), packaging material, rodent traps, records of animals in the traps, and review completed sanitation worksheets.
- Record stock rotational practices, such as "first in first out."
- Determine how long product remains unrefrigerated in the packing facility before it is cooled. If not cooled at the packing facility determine the time interval before the product is held under refrigerated conditions, either in a refrigerated transport vehicle or other refrigerated storage or processing facility.
- Take product temperatures if possible.

FOOD ADDITIVES OR PESTICIDES

Any substance intentionally added to food, or reasonably expected to become a component of food, is deemed an additive and requires pre-market approval from FDA unless it meets one of the exceptions to the food additive definition (section 201(s) of the Act). Exceptions for farm use are substances whose use is generally recognized as safe (GRAS), and pesticide chemicals or their residues.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) definition of a pest includes microorganisms, except when they are on processed food or on humans or animals. FDA and EPA have agreed that the following post-harvest activities do not constitute processing: foods subjected to washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, and removal of leaves, stems, and husks. Thus, antimicrobial agents are considered pesticides when used to treat raw agricultural commodities or water and subject to registration under FIFRA.

For further information regarding EPA/FDA jurisdiction over antimicrobial agents used with foods see: http://www.cfsan.fda.gov/~dms/opa-antg.html#4

COOLING

Product cooling may be performed at the farm, at a geographically separate packing facility, or by another firm. If cooling is conducted by another firm you will need to extend your investigation to that firm (e.g. condition and source of ice).

The type of cooling method will determine the degree of microbial risk for product contamination. Types of cooling include room cooling, forced air cooling, hydro-cooling, package icing, and vacuum cooling. Generally, the greater the contact between product and water (submersion, floating, spray) the greater the risk of contamination. Water that is reused (e.g. hydrocooler, chill tank) carries a greater risk because of the potential for pathogens to build up. Submerging warm product in cold water may also result in infiltration of water and pathogens, if present. Refer back to the water section of this guide for critical areas to consider. Air and vacuum cooling present the lowest risk for contamination, although air introduced in cooling systems can represent a potential microbial hazard by the introduction of microorganisms found in dust and tiny water droplets in the air. These microorganisms can come from outside dust, soil, equipment, and waste products.

- Record the source of water used and sanitary conditions in the manufacture, transport, and storage of the ice
- Record contact time and temperature parameters.
- Identify potential sources of contamination and opportunities for cross contamination.
- Examine conditions of product storage, including floors and pallets.
- Take final product temperatures if possible.

TRANSPORTATION

Conditions of transport both from the field to cooler and packing facility, and from the packing facility on to distribution may provide opportunities for microbial contamination and proliferation of pathogens. This section will focus on field transportation since transportation from packing facility on to distribution is typically covered in a GMP type inspection. The same principles apply to both levels of transportation.

- Record sanitation conditions such as dirt /debris on vehicle, prior loads hauled (manure, trash, animals), type and frequency of cleaning and sanitizers used.
- Determine the time from harvest to packing and next point in the distribution chain.

In some operations, the truck bed in the field may be a food-contact surface.

SAMPLING AND ANALYSIS

Collect samples that will support your observations. Do not collect microbial samples unless you suspect contamination.

Samples must be collected in an aseptic manner (IOM 4.3.6), and sample integrity maintained. Typically, environmental sampling plays a large role in farm investigations. The goal is to find sources that led to product contamination, and not focus on obtaining contaminated product. This is not to say that finished product shouldn't be collected, but in farm investigations the emphasis is on determining sources of contamination.

Examples of when you would collect samples include: water samples from a well of suspect design, suspected surface water contamination of wash water to the packing facility, and soil/biofilm or bird dropping accumulation on, or in equipment. One inspection found opossum feces in a hydrocooler. Typically, the farm inspection occurs several months after the harvest of the implicated product so it is not useful to collect clinical worker samples (this would be performed by the health authority, not FDA).

Do not collect water samples unless they can be analyzed within 24 hrs. (See IOM 4.3.6.3) If the water source is treated with any disinfects, such as chlorine, use sodium thiosulfate to inactive any residual disinfectant.

Live animals including invertebrates will not ordinarily be collected. However, if investigators receive a

request for collection live animal samples or decide such collection is necessary, they must notify and obtain concurrence from OCM/OEO, ORO, and CFSAN.

If product samples are collected for salmonella or pesticide analysis see IOM Sample Schedule Chart 1 and 3. For other analysis the microbiologist on the team needs to determine sample size. Note for foreign investigations it is not necessary to collect a 702 b sample, and the required sample size may be smaller than normal. Consult with ORO/CFSAN for sample size for foreign inspections.

If using a foreign laboratory make arrangements to receive lab results.

ON-FARM TRACEABILITY

Verify implicated shipments and product information. Document the system and coding that allows the product to be traced from the field to packing facility through loading and distribution. Basic information should include crop, field identification, harvest date, harvest crew, lot identification or product code, shipment dates, and customers.

DOCUMENTATION

Obtain and review records for the time period when the implicated product was planted, harvested, packed, and cooled. If time allows and if appropriate to the purpose of the investigation, obtain records for the current operation.

Obtain copies of all documents from the firm and other agencies (municipalities, local health clinic) that support investigational observations and sources of contamination relating to the pathogen involved in the foodborne outbreak, or positive produce sample. Examples of records include:

- Water: microbial testing for all water sources in both the field and packing facility, well design diagrams.
- Manure/Field prep: Fertilizer and pesticide application records, soil amendments (focus on last few applications before harvest), specification sheet (time/temp).
- Worker health: local disease surveillance, employee training records, absentee records for both field and packing facility personnel.
- Sanitation: Invoices for removal of waste from portable toilets, logs for cleaning/sanitizing /supplying restrooms, field equipment (bins, sacks), and equipment in packing facility.
- Processing and packing: disinfectant and pH levels in packing and processing water, sanitation, any product or environmental testing. Temperature logs for cooling product, if applicable, type and number of pests in field and packing facility.
- Transportation: cleaning routine for field and export trucks, refrigeration temperature logs as applicable.
- Traceback: records documenting the system used for tracing product back from distribution chain to packing facility and field.
- Identify responsible parties for all aspects of operation (i.e. worker training, master sanitation schedule, etc).

INVESTIGATION CLOSE-OUT

Discuss all observations, including those that apply to Good Agricultural Practices and GMPs. Emphasize that GAPs are only guidance, not regulation. Explain how observations relate to possible microbial contamination of the product and potential illness. Bear in mind that produce is typically eaten raw and there's no thermal treatment to reduce pathogen levels.

COMPLETING THE FDA 483

A FDA 483 may be issued for either domestic or foreign firms. Keep in mind that farming operations and packing facilities or other buildings may not be subject to the requirements of 21CFR Part 110 (see Legal Basis section of this guide). All observations listed must be based on objectionable conditions or practices observed by the investigator that indicates food consists in whole or in part of any filth, putrid, or decomposed substance [402(a)(3)], or has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health [402(a)(4)].

- Do not cite 21 CFR 110 for excluded operations.
- Do not directly refer to Agency guidance documents in written observations (see IOM 5.2.3) including "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," October 1998 (GAP Guide)
- Make sure that the status of the operation at the time of the observation is noted (e.g. fields are plowed, product harvested, packing facility not in production).

Some examples of FDA 483 observations:

- On <date>, "I observed non-human feces on waxer brushes, a food contact surface within the packing facility.
- On <date>, I observed two employees use the restroom facilities and return to handling whole produce without washing and sanitizing their hands.
- On <date>, during the sorting/inspecting of produce, I observed six birds nested directly above the packing facility tables while produce was sorted, and residues of what appears to be

bird feces on the food contact surfaces of the sorting table.

If you have any questions about items to cite on the FDA 483, please contact the lead district supervisor, OCM/OEO or DFI.

DEBRIEFING AND REPORTING

DEBRIEFING

The team will have a debriefing conference call with the District, OCM/OEO, DFI and CFSAN within 5 days of the completion of the farm investigation. The lead investigator will arrange the conference call through OCM/OEO. Investigators will report the details of their findings on these calls.

EIR

The EIR should contain sufficient detail to demonstrate how unsanitary conditions observed contributed to, or may have contributed to contaminating the product (Reference IOM 5.4.7.1, 5.4.7.2, and 5.4.7.3). For example: "human feces with toilet paper were found within 10 feet of the edible crop that was being harvested" or "water used for spray irrigation of the lettuce is supplied by a river that has raw sewage inputs from 10 towns upstream, and there is no wastewater treatment prior to use".

The EIR will follow the format prescribed in the IOM with additional headers as contained in the Farm Investigation Questionnaire. A section entitled Analytical Results, providing a summary of analytical results may be provided in the EIR. The Questionnaire should be included as an attachment, or at a minimum, all questions answered in the EIR.

If there are multi-site investigations and it appears district/ or ORA/Office of Enforcement timeframes will not be met, the lead investigator should discuss the estimated time of completion of the EIR with district management and OCM/OEO. In any case the timeframe should not exceed 60 working days.

REPORT DISTRIBUTION

For both domestic and foreign investigations the EIR is endorsed by the district of the lead investigator.

For domestic investigations, the original EIR, including all exhibits and photos, and the Questionnaire should be submitted to the home district compliance branch. A hard copy of the EIR, including all exhibits and the Questionnaire should be submitted to CFSAN, Division of Enforcement, Domestic Branch (HFS-607), and an electronic copy of the report without exhibits should be sent to OCM/OEO (HFA-615). HFS-607 is responsible for further distribution at CFSAN.

For foreign investigations the original EIR should be submitted to CFSAN, Division of Enforcement Imports Branch, (HFS-606), with a copy to DFI with exhibits, and OCM/OEO (without exhibits). HFS-606 is responsible for further distribution within CFSAN.

FDA is interested in sharing the findings of the investigation after appropriate redaction with the firm and other government agencies. This is consistent with our education and outreach approach with industry in improving farm practices to reduce microbial risk of contamination of fresh fruits and vegetables.

For domestic investigations the home district sends the FMD-145 copy to the firm. For foreign investigations HFS-606 provides it to the firm and to the foreign authority if a confidentiality agreement is in place.

ATTACHMENTS

Note: Attachment 2-11 are not directly attached to this PDF copy of the guide. They are separate documents that are available at the web links identified below.

1. Generic Sampling Equipment List
2. Form FDA 3623-Farm Investigation Questionnaire
3. Form FDA 3623a-Additional Water Source Form
4. Form FDA 3623b-Additional Workers Form
5. *IAFP Form G1 -"Illustration of Contamination Flow"
6. *IAFP Form G2 - "Record Review of On-site Investigations and Test Results Prior to and During Outbreak"
7. *IAFP Form G3 - "Source and Mode of Contamination of Surface Waters"
8. *IAFP Form G4 - "Source and Mode of Contamination of Ground Waters"
9. *IAFP Form G5a - "Disinfection Failures That Allowed Survival of Pathogens or Toxic Substances"
10. *IAFP Form G5b - "Source of Contamination and Treatment Failures That Allowed Survival of Pathogens or Toxic Substances"
11. *IAFP Form G6 - "Sources and Modes of Contamination During Distribution and at Point of Use"

***Attachment 5-11 Reprinted with permission from** *Procedures to Investigate Waterborne Illness,* **Second Edition 1996. Copyright held by the International Association for Food Protection (IAFP), Des Moines, Iowa, USA. Booklet is available for purchase-see reference # 9 below.**

The required questionnaire forms, identified in this guide as Attachment 2-4, should be obtained from the FDA Internet Forms page.

- ATTACHMENT 2 - Farm Investigation Questionnaire (FDA Form 3623) http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3623_508.pdf

- ATTACHMENT 3 - Form for additional water source reporting (FDA Form 3623a) http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3623a_508.pdf
- ATTACHMENT 4 - Form for additional worker health and hygiene reporting (FDA form 3623b) http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3623b_508.pdf

ATTACHMENTS 5-11: Copies of IAFP forms G1-G6, are available at: http://www.fda.gov/ora/inspect_ref/igs/farminvestguide_attach5-11.pdf (or alternative text version) linked from the web version of this inspection guide.

REFERENCES AND WEBSITES

1. Inspection Guide and copies of IAFP forms G1-G6 from *Procedures to Investigate Waterborne Illness,* Second Edition 1996*,* , http://www.fda.gov/ora/inspect_ref/igs/iglist.html

2. Farm Investigation Questionnaire(s), http://www.fda.gov/opacom/morechoices/fdaforms/ora.html

3. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, http://www.foodsafety.gov/~dms/prodguid.htm

4. Guide at a Glance, FDA, http://www.cfsan.fda.gov/~dms/prodglan.html

5. Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations, April 2001, FDA, http://www.fda.gov/ora/inspect_ref/igs/epigde/epigde.html

6. GAPs resources at Cornell University, including Food Safety Begins at the Farm, http://www.GAPs.cornell.edu

7. Investigations Operations Manual, FDA, http://www.fda.gov/ora/inspect_ref/iom/default.htm

8. Foreign Agriculture Service provides various countries' health and agricultural infrastructure. http://www.fas.usda.gov/scriptsw/attacherep/default.asp

9. Oxidation reduction potential (ORP) technical information at http://ucce.ucdavis.edu/freeform/UC_GAPs/documents/Water_Disinfection1892.pdf

10. Procedures to Investigate Waterborne Illness, 2nd Edition
    Procedures to Investigate Foodborne Illness, 5th Edition IAMFES,
    Booklets available for purchase from The International Association for Food Protection, 6200 Aurora Ave., Ste 200W, Des Moines, IA 50322. Phone: 800.369.6337, Fax 515.275.8655, website: http://www.foodprotection.org

11. Post harvest info and GAPs: http://postharvest.ucdavis.edu and www.ucdavis.edu

12. Water standards and resource information, http://www.epa.gov/ebtpages/water.html

ATTACHMENT 1
Generic Sampling Equipment List for Farm Investigations

I. General Overview

Produce farm inspection, conducted by teams comprised of investigators and scientists (microbiologists, chemists, water expert/sanitarians, epidemiologists), must be equipped with appropriate supplies to collect farm samples and specimens targeted or implicated in food-borne outbreaks. Investigative teams must identify before and during the farm inspection, representative samples needed to give the highest probability/detection of suspect pathogen or chemical substance. Any samples collected for microbiological analysis need to be collected aseptically and include appropriate sampling equipment controls. The sample needs to be properly stored and transported to maintain sample integrity.

In general for water samples: examine for total coliforms, fecal coliforms, *E.coli*, and *Salmonella*. Product samples may be minimal due to unavailability of product, or resource and transport difficulties. Focus on pathogen specific testing for product, such as *Salmonella*. For swabs, examine for *Salmonella*, and possibly others as determined through consultation with the analyzing lab. Be sure to request speciation.

II. Materials/Equipment

Quantity	Item
2 rolls	FDA Labels
2 rolls	Tape, non-label
4	Permanent Markers (Sharpies)
1 box each	unopened Garbage bags and tall kitchen bags (household type)
1 roll	String/twine
8	Gel paks (use judgment)
2	Coolers
8	Hair Nets
1 box each	Medium Gloves - sterile and non-sterile
2	Sterile Sleeves - that are autoclaved beforehand
2	Sterile Spoons - Scienceware
6	Sterile plastic scoopers/trier - Scienceware
1, 2, 2	Autoclaved forceps, spatula, knife
1 bag	10 ml sterile graduated Pipettes (plus one bulb)
4 each	WHIRL-PAK bags -- all sizes - Nasco
6	Thio Bags - Nasco WHIRL-PAK (for water sampling 100 ml minimum)
20	Combination of Sterile 250 ml wide mouth bottles (Nalgene), and sampling cups (look like specimen cups, often Falcon brand)
2	Thermometers - 1 degree accuracy, probe type, & calibrated
2	pH paper (range 1-14 with 0.5 sensitivity, or 1 pH unit sensitivity)
2	Chlorine test kit, free and total, to cover appropriate range (0-2.5ppm and approx100-500 ppm)
20	TECRA Enviroswabs
5	Moore swabs
1 box	Alcohol on a square - Some type of surface disinfectant - (i.e. HYPE-WIPE by Bioscreen; towelette saturated with Sodium Hypochlorite prediluted to 0.525% and there is also EXTRA STRENGTH which is prediluted to 1.05%), or jar of alcohol for disinfecting pipes for water collection.

Generic Sampling Equipment List for Farm Investigations (cont.)

Other Equipment

1. Officials seals rolls (2)
2. Calculator (2)
3. Paper towels (one roll)
4. Digital cameras (3)
5. Flashlight (2)
6. Non-sterile scissors (2)
7. Knapsacks and tall kitchen bags for carrying items into field (1 box)
8. Pocket Army knife (2)
9. FedEx airbills (6)
10. Steel blade tape measure (2)
11. Insect Repellant, Sun block
12. OTC meds from Health Unit (aspirin, antihistamine, anti-diarrheal, ibuprofen)

Other

Field Kit - contact John Guzewich, Director, CFSAN Emergency Coordination and Response Staff, Office of Compliance @301-436-1608 (e.g., free residual chlorine test strips, dye tablets, walkie-talkies, 2 GPS units)

Sample/Specimen Transportation and Field Laboratory Notification/Coordination -
Lead investigator and Microbiologist Team member

Sample/Specimen Preparation and Analysis - ORA Lab, as designated by Division of Field Science (DFS)