



**Inspection Process, Inspection Workflow  
and Inventory Maintenance**

Effective Date:

Approved By: Russell Lilly  
Manufactured Food Program Manager

Date: 2-4-2014

Approved By: [Signature]  
Bureau Chief

Date: 2/4/14

**I. Purpose**

The purpose of this procedure is to outline the process by which the Manufactured Food program manages inspections. This system provides the foundation for inspecting manufactured food firms to determine compliance with applicable food safety laws and regulations.

**II. Acronyms/Definitions**

Acronyms, abbreviations and definitions that may be encountered in the program include:

- OOB** Out of business
- OEI** Official establishment inventory, FDA speak for the list of firms we inspect
- NOEI** Not official establishment inventory, firms where FDA may have jurisdiction but they are not inspected as a manufactured food firm
- OAI** Official action indicated, one of three possible inspection categories (with NAI and VAI) these are firms that if correction is not forthcoming enforcement actions will be initiated
- NAI** No action indicated, a inspection classification where no violations were noted
- FD&C Act** The food drug and cosmetics act, a primary federal food safety law first enacted in 1938
- VAI** Voluntary action indicated, a inspection classification where violations were noted but no immediate enforcement action is anticipated
- FEI** Facility establishment identifier, a unique number assigned to each establishment
- eSAF** Electronic state access to FACTS, which is FDA's electronic database for all of the firms they regulate
- FSMA** Food safety modernization act, a significant revision and update to the food drug and cosmetic act that was enacted in 2011
- ALERT** A voluntary program for the food industry promoted by FDA to raise awareness of food security issues
- RFR** Reportable food registry, a federal requirement that management of food firms notify FDA if food safety hazards are identified in product they have produced



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 2 of 32

Effective Date:

2-4-14

<b>SSOP</b>	Sanitation standard operating procedures, the written procedures a firm utilize to describe their equipment cleaning and other sanitation actions
<b>LACF</b>	Low acid canned foods, foods with a relatively neutral pH that are placed in a hermetically sealed container, these must comply with 21 CFR 113
<b>CIP</b>	Clean in place, a method of cleaning large pieces of equipment like pipeline systems or tanks that cannot be cleaned in a three compartment sink
<b>FDA credentials</b>	Documentation showing that a person has been commissioned by FDA, privileges granted may include the ability to perform inspections under federal authority or to view information that is not available to the public
<b>E40a, E40b</b>	The first and second pages of the Manufactured Food Inspection Report form
<b>FDA 482</b>	Notice of inspection form, presented to firms when an inspection is conducted under FDA authority
<b>FDA 483</b>	Inspectional observations, the written notice of violations presented to a firm when violations are noted during the inspection

### III. Responsibilities

#### A. Program Management

1. Provides oversight of inspection program.
2. Identifies inspections that need to be performed.
3. Reviews and approves inspection reports.
4. Communicates and collaborates with the FDA.
5. Audits inspection process and assigns audits.
6. Provides status updates/tracks and trends inspection data.
7. Assists in enforcement actions.
8. Provides training and guidance to inspectors as needed.

#### B. Inspectors

1. Perform the inspection and enforcement procedures per procedure.
2. Follow reporting process for documenting inspections.
3. Submit inspection paperwork within established timelines.
4. Provide education and support to industry to enhance understanding of and compliance with public health regulations.
5. Notifies program management of public health concerns at regulated firms.

	Bureau of Environmental Health Services Manufactured Food Program	
	<b>Inspection Process, Inspection Workflow          and Inventory Maintenance</b>	Page 3 of 32
		Effective Date: <i>2-4-14</i>

**C. Administrative Support Staff**

1. Scan inspection reports and FDA Form 482s.
2. Place scanned copy copies of inspection reports in the database and in the network folder.
3. File paper copies of inspection reports in the firm's inspection folder.
4. Maintain manufactured food inventory lists and inspections in database.

**IV. Program Elements**

The Bureau of Environmental Health Services performs Contract and Non Contract Inspections. Contract inspections are inspections that are assigned to and performed at the request of the FDA based on contractual agreement. All other inspections are Non Contract Inspections.

**A. Risk Based Inspection Program**

The Manufactured Food Program maintains an inventory list of all manufactured food facilities in Missouri. This inventory is categorized by degree of risk associated with the likelihood that a food safety or defense incident will occur.

Non Contract Inspections are prioritized, assigned, and resourced based on risk categories assigned to the facility or product, the manufacturing processes, and the inspection history of the facility.

Priority for inspections is based upon numerous factors, such as:

- consumer complaints;
- facility size;
- whether the plant handles one or more of the eight major food allergens (dairy, wheat, egg, soybean, fish, peanuts, tree-nuts and crustaceans- which include; shrimp, crabs, lobster and crayfish);
- if the plant has been implicated in a food-borne disease outbreak;
- the type of food produced such as bottled water and/or potentially hazardous foods; and
- inspection history.

The FOOD PROCESSOR PUBLIC HEALTH PRIORITY ASSESSMENT WORKSHEET found at the end of this policy is used for determining a firm's risk level.

**The targeted frequency for inspections is:**



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 4 of 32

Effective Date:

2-4-14

1. High risk facilities are inspected at least once every twelve months.
2. Medium risk facilities are inspected at least once every twenty-four months.
3. Low risk facilities are inspected at least once every thirty-six months.

**B. Inspection assignments**

The manufactured food program has contracts and participation agreements with FDA. Accomplishing the required number of inspections in a timely manner is a top priority. Program management will send lists of inspections to be performed to each regional EPHS V quarterly. They are to assign the inspections to individual inspectors and provide the program with a projected completion date for each inspection. Program management will provide reports to the regional EPHS Vs and bureau management on a routine basis documenting the status of the program.

**V. Workflow**

Meeting FDA contract deliverables is vital to the food processing program. Not only does it provide a major revenue stream for the program, but it contributes to good public health by assuring a safer food supply for the consumer. The following timelines are to be met by all food processing inspectors in the DHSS manufactured food program:

- A. Upon completion of an inspection, the inspector will leave the white copy of the inspection report with the facility. The inspector will keep the pink copy of the report for their file and mail the yellow copy of the inspection form along with the FDA 482 (for contract inspections) to the central office upon return to their home office but not to exceed 5 business days of the inspection.
- B. Inspectors will enter inspection reports into eSAF no later than 10 business days after completion of the inspection.
- C. Once the inspection report is received in the central office, the administrative staff will scan the inspection reports and attach them to the inspection record in the database. The report will be saved in the network file and the paper copy filed in the folder for the firm.
- D. Program Management will review and approve the reports entered into eSAF and submit them to FDA, within 10 business days of the inspector entering them into eSAF.

**VI. Inspection Preparation**

**A. File Review**



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 5 of 32

Effective Date:

2-4-14

The files and records for regulated facilities are a wealth of information and are the first place you should go for information about an upcoming inspection. Before any field visit or inspection, always review eSAF for past inspection history as well as the paper file and/or electronic file on the O: Drive. The review should include looking at:

1. General facility information: the name of the owner or manager, the facility street address, hours of operation, product(s) manufactured, etc. Knowing the hours of operation of an establishment is critical, as inspections should normally be conducted when the facility is processing product. Some facilities should occasionally be inspected when not in production to enable a review of equipment construction and cleanliness. The decision as to if the plant should be in production should be made in advance of the inspections and the timing of the inspection be made to achieve the desired conditions.
2. Date and time of the last inspection. Occasionally mistakes happen and even though a contract inspection has been assigned to us at the state, FDA will perform an inspection. It is far better to discover this by a record review than at the facility. Conducting food inspections at different times of day at each visit may allow the investigator to observe different staff or different foods prepared.
3. Review of the establishment's inspection history. By reading the file, the investigator can become familiar with the facility and its previously noted violations. A copy of the most recent inspection report will be essential in the field to determine which violations have been corrected and which are ongoing problems. It will also provide information on whether there are safety concerns. By reviewing the information in eSAF, it can also be determined if there are consumer complaints about the firm's products. Do not take the only copy of the file from the office into the field, as its contents could be damaged or lost.

#### B. Out of Business and Not OEI Facilities

Out of Business Facilities (OOB) are defined as firms that are no longer in business for reasons other than having moved.

Not Official Establishment Inventory (Not OEI) establishments are defined as those that no longer engage in food manufacturing, but still remain in business. For example, a facility that used to have a grain elevator but now just sells feed and fertilizer would be considered Not OEI. NOTE: If a facility is no longer



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 6 of 32

Effective Date:

2-4-14

engaged in food manufacturing but still produces products subject to FDA regulation (for example pharmaceuticals) the program manager will code the item as OTHER in eSAF but the inspection will still be coded as Not OEI in the State manufactured food inventory list. If an inspector has a question about what to categorize an establishment, contact your regional EPHS V or program management for guidance.

To verify a facility is no longer in business several of follow-up steps should be utilized:

- checking the Missouri Secretary of State's website for active business registration to find the firms official point of contact for the business license;
- visit(s) to the physical address;
- a telephone call to the last known telephone number;
- a review of the facility file for other contact telephone numbers and names;
- a search of the local telephone and business directories;
- an internet search for other locations or contact information; and
- contact other sources such as the local post master, Chamber of Commerce, Realtors if there is an indication that they have a connection to the property, landlords, local police departments, etc.

When an inspector determines that a facility is Out of Business or Not OEI, the followings steps should be followed:

1. Inspector will email Program Management and copy Administrative Support, stating the following:
  - name of the firm;
  - FEI number;
  - date of the investigation; and
  - results of the investigation (all information that would have been put into the endorsement or inspection summary in eSAF), including how it was determined that the facility is OOB or Not OEI, i.e. field visit, internet search, phone call etc. The name and title of the person who told you the company was out of business should be included.
2. Inspector will put "OOB firm" or "Not OEI firm" in the subject line of the email and send it HIGH PRIORITY.
3. Program Management will go into eSAF to the Assignment Detail and enter the information in the "Request FDA Update" section.
4. Administrative Support will enter information in the Manufactured Food database from the inspector's email

### C. Supplies



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 7 of 32

Effective Date:

2-4-14

Gather the appropriate paperwork. This should include blank copies of the following forms; Manufactured Food Program Inspection Report E40 and E40A, Notice of Inspection 482 forms, Order of Embargo E19.0, and Sanitation Observation E6.07. Other essentials include; Food Processor Public Health Priority Assessment Worksheets (Included in Appendix), FDA credentials, State employee identification badge, business cards, and any contractually mandated FDA handouts, like the RFR information, FSMA information, ALERT program information, and information about food facility registration under the bioterrorism act.

Bring water sample bottles and a cooler with ice packs if the facility is or may be served by a non-community water supply. Water samples must be delivered to the State Public Health Laboratory by Friday morning.

Equipment necessary for inspections varies, depending on the type of inspection, but will include in general a clipboard, flashlight, pens and copies of the applicable rules for reference. A camera can be a useful tool for any type of inspection. See evidence collection section for details on camera use.

As the agency advances technologically, the necessary equipment list may change to include extra printer cartridges, blank paper, the computer and printer, as well as power supply cords or car chargers.

Specific equipment needed for a food safety inspection include: alcohol prep pads or sanitizing wipes, dial-stem thermometers, a thermocouple, maximum registering waterproof thermometer, heat-strips or Thermo labels for a dish machine, test strips for sanitizers, and a hat or hair restraint.

#### 1.) Thermometers

Thermometers may be used to determine if food is adulterated potentially leading to thousands of dollars worth of food being discarded. As such, it is essential that they be accurate. Each inspector is issued a Thermapen® digital thermometer it should be the thermometer used for official regulatory work. A bimetal dial-stem thermometer that has been tested and calibrated may be used as an emergency backup. Thermapens® are preferred for most activities because they are easy to use, fast, accurate, and have NIST-traceable calibration certificates.

Each thermometer that may be used for regulatory work must have its accuracy verified two ways. At least monthly (first of each month recommended) each inspector should test their thermometer with a ice point test. Fill a large cup or other suitable container with ice (crushed ice is ideal) and nearly fill with water, agitate vigorously for a few minutes, insert the probe of the thermometer to be tested and continue to gently stir the ice slurry with the thermometer for a few



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 8 of 32

Effective Date:

2-4-14

minutes. Verify that you are getting a stable reading. Please view the video found at: <http://www.thermoworks.com/blog/2011/05/truth-about-ice-baths/> for more information on performing an ice bath verification correctly.

Each July all thermometers must be sent to the State Public Health Laboratory where the Environmental Bacteriology unit will verify the accuracy of each thermometer. The Laboratory will supply shipping boxes and mailing labels to ship the thermometers. The regional EPHS V should coordinate this activity for each district office. It is recommended that half of the thermometers should be sent to the lab early in the month and the other half when the first batch has been returned. Results of the yearly laboratory calibration checks will be kept in the manufactured foods program database.

All thermometers in use must be accurate to +/- 2°F; a thermometer not meeting this standard must be recalibrated or replaced.

## VII. Beginning an Inspection

Unannounced inspections are preferred; however, announced inspections are acceptable in situations such as, new establishments, follow-up inspections, seasonal/part-time operations, or at facilities that operate at odd hours and are a great distance from the inspector performing the inspection. Be sure to dress professionally and appropriately for the facility being inspected.

### A. Introductions

When beginning an inspection, contact the facility manager or person-in-charge upon arrival. Introduce yourself, making sure your State Identification Badge is visible. Present one of your business cards, and explain the reason for your visit. You should do this verbally for every inspection.

*An example: "Good morning/afternoon, I am \_\_\_\_\_, with the Missouri Department of Health and Senior Services. (Present a business card) I am here to do a routine inspection. May I speak with the manager or person-in-charge?"*

You may also ask specifically for the person who accompanied the inspector on the last inspection.

Document the name and title of the person to whom credentials were shown and the persons authority to receive the notice, report their full name with middle initial. Credentials must be shown and the 482 Notice of Inspection issued to the most responsible person at the firm who is present at the time of the inspection.

	Bureau of Environmental Health Services Manufactured Food Program	
	<b>Inspection Process, Inspection Workflow          and Inventory Maintenance</b>	
	Page 9 of 32	Effective Date: <i>2-4-14</i>

**B. Additional Preliminaries**

At times a firm will want a record of who was in their facility and may ask to copy your employee identification badge or FDA credentials. You MAY allow them to copy your DHSS employee identification badge but SHALL NOT allow copies to be made of your FDA credentials.

With small firms it is recommended to begin the inspection immediately. For larger firms a preliminary interview is advisable. This is the time to discuss what products are made, the layout of the plant, review pest control logs, HACCP plans or other necessary documents. Provide the firm with any necessary information as required in our FDA contract (e.g. FSMA reinspection fee information sheet) and collect any additional information needed to complete a eSAF report. Many of these functions will occur at the exit interview of small firms.

**VIII. Performing the Inspection**

Invite the owner or manager to accompany you during the inspection. It is preferred someone from management escort you through the facility during an inspection which is good way to determine if the manager is aware of environmental health laws and regulations. Having the manager with you also allows corrections of problems during the inspection when practical. However, a manager may try to distract you in the hope that fewer violations will be noted; therefore, maintaining your own pace and focus throughout the inspection will prevent you from being steered off course. Be conscious of safety issues such as forklifts being used or complex equipment operating in your vicinity.

Following a logical path or route through a facility can help to make sure your inspection has been thorough. For instance, by following the flow of product through a food facility from receiving through production, packaging, warehousing and shipping, the investigator can think about environmental health concerns at every step of the way without missing important areas. Devising a standardized system for each type of facility will help to perform thorough and complete inspections.

If available, take along a copy of the previous inspection to follow up on objectionable conditions noted. Problems that were cited on the last inspection report should have been corrected by the current inspection. The investigator will need to note which problems are ongoing.

During the inspection (including the preliminary and exit interviews) the inspector must capture the following information to be able to fill out the Manufactured Food Program Inspection Report (E40), the FDA eSAF report and the program database.



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 10 of 32

Effective Date:

2-4-14

1. Verify the firm's establishment data (address, phone numbers, etc).
2. Document the firm's legal corporate name, not just the name the plant is operating under, street address, mailing address, telephone number and email.
3. Check one of the three boxes on the form for the reason for inspection
  - a) Initial: The first time that a facility new is inspected.
  - b) Routine: Inspection of a facility that has been previously inspected where the assignment was generated based on time since last inspection. This designation is also used for an establishment that has existed for some time but has no previous inspections.
  - c) Follow-up: Inspection that has been scheduled to follow-up on violations documented from a previous inspection.

And/or

- d) Complaint (if applicable): Inspection that is being performed as a result of a complaint the department has received and is investigating.
4. Document the most responsible plant official (name and title).
5. Document the products and processes performed in the facility. Determine what product and processes are in production at the time of inspection. For small to medium sized firms the entire operation should be inspected, larger firms may require specific products or processes be selected to be inspected. These should normally be the most sensitive/hazardous product/process being produced on the day of the inspection.
6. Document the plant representative(s) that accompanied you during the inspection (name and title) and their duties.
7. During the inspection, document the plant's hours/days/season of operation.
8. Review the firm's system for product and lot coding.
9. Document significant changes (e.g. personnel, facilities, products, processes since the previous inspection.
10. Document who the FSMA sheet was given to.
11. Address Food Defense Security Preventative Measure Guidance and provide RFR guidance documents including the ALERT card.
12. Inquire if the firm has registered with the FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and whether registration information is current. If they have not or if the firm information needs updating, leave information on how to register/update.
13. Determine if previous discrepancies have been corrected.



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 11 of 32

Effective Date:

2-4-14

14. Review the firm's recall and complaint records if they are available.
15. Conduct the actual inspection, making notes, asking questions and following the flow of the process from incoming raw ingredients to production to packaging, warehousing and shipping.
16. Perform reconciliation exam where applicable.
17. Assess employee activities critical to the safe and sanitary production and storage of food.
18. Evaluate the likelihood that conditions, practices, components and or labeling could cause the product to become adulterated or misbranded.
19. Where significant violative conditions or practices are present record findings. Document objectionable conditions or practices in sufficient detail so someone reading the report will clearly understand the observations and significance. Write findings accurately, clearly and concisely.
20. State observation and give recommended corrective actions if appropriate. Alert the firm's person in charge when an immediate corrective action is necessary. Record management's response or corrections.
21. Number your observations (1, 2, 3..., this is in addition to the citation of the regulation).
22. When violations are noted include a complete citation of the particular part of 21CFR 110 that is being violated. For example, if a firm has a bathroom that opens into a production area that does not have a self closing door the citation will be 110.37(d)(3). For violations other than 21CFR 110 reference the regulation. For example per seafood HACCP 21CFR 123.
23. Document date of follow-up, if needed.
24. Perform an exit interview with plant representative. Management must be advised regarding defects found and corrective action to be taken at the conclusion of the inspection.
25. Remind management of their responsibility to comply with the FD&C act.
26. Answer any questions clearly and in an informative manner that management may have regarding the inspection or corrective actions needed for violative conditions noted during the inspection.
27. Leave the original (white copy) of the inspection report form E40 with the firm.
28. If it is suspected that the risk level for the facility has changed complete the Food Processor Public Health Priority Assessment Form. (This form will be mailed with the inspection form to the office so the database can be updated.)

**IX. FDA Contract Inspections**

Before conducting a FDA contract inspection we must establish proper jurisdiction. Begin by asking what percentage of product shipped leave the state



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 12 of 32

Effective Date:

2-4-14

of Missouri (interstate commerce) document the answer on the inspection report form. If the answer is "0" further questions should be asked. Determine if any ingredients or packaging material originate from sources outside Missouri. Document these answers in the narrative section of the inspection report.

In order to fulfill contract requirements for FDA contract inspections, the inspection must be entered into the FDA's eSAF database. The following list includes the information required in the endorsement and inspection summary sections of the database and should serve as a guide when performing inspections

**A. Endorsement**

- The reason for the Establishment Inspection , i.e., workplan.
- A brief history of previous findings including classification of previous EI, any action taken by the district and/or state and/or corrective action taken by the firm in response to inspectional observations from the previous inspection.
- A concise summary and evaluation of current findings and samples collected.
- Refusals, voluntary corrections or promises made by the firm's management.
- FSMA sheet ("A copy of the FSMA User fee sheet was given and discussed with management.")
- FD&C warning statement given to management
- Classification and follow-up consistent with inspectional findings and Agency policy including notification of other districts/states and headquarters as warranted.

**B. Inspection Summary (written in first person)**

- The reason for the inspection
- The firm's legal name (and DBA if applicable), street address, mailing address and telephone number.
- The date, classification and findings of the previous inspection
- The actual inclusive dates of the inspection
- The name of the person to whom credentials were shown and the Notice of Inspection was issued and the person's authority to receive the Notice. Explain if you were unable to show credentials or issue forms to top management (Report Full Name with Middle Initials and Titles). Include the name of the person and mailing address to whom FMD-145 correspondence should be directed; include to whom the **FSMA sheet** was given to, as well as the state form and/or 483



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 13 of 32

Effective Date:

2-4-14

- The scope of the inspection; i.e., surveillance/juice/environmental sampling; describe what the firm actually does (warehouse/manufacturer/repacker/juice/seafood/LACF/acidified/retorts on site/any specialized equipment) and go into a brief description of the products, processes or systems, documents covered during the inspection; the manufacturing codes/lot numbers and if necessary their interpretation.
- Significant changes (e.g., personnel, facilities, products, processes) since the previous inspection
- BT Registration Status
- Food Defense Security Preventive Measure Guidance addressed
- RFR guidance documents provided
- Reconciliation exam completed  
(<http://www.fda.gov/ICECI/Inspections/IOM/ucm122532.htm>)
- Recalls (negative responses needed)
- Complaints (negative responses needed)
- Summary of where samples were collected and potential route of contamination (if collected)
- The significant findings if any
- Management's response or corrections
- Warnings given to management (FD&C warning statement given to management)

All inspections with violations noted should in addition to the information required for non-violative reports contain the following:

1. The objectionable conditions or practices described in sufficient detail so someone reading the report will clearly understand the observation(s) and significance.
2. The objectionable conditions or practices cross-referenced to the state report, samples collected, photographs, or other documentation including exhibits attached to the inspection report.
3. Information as to when the objectionable conditions or practices occurred, why they occurred, and who is or was responsible, developed to the highest level in the firm.

All FDA contract inspections must be classified. The classifications will be; NAI for inspections with no violations noted, VAI for inspections with violations but no immediate pending enforcement actions anticipated and OAI for inspections when a work order or closing order is issued.

**X. Inspection Criteria**

**A. GMP Inspections**



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 14 of 32

Effective Date:

2-4-14

When performing an inspection of a processor under Current Good Manufacturing Practices (CGMPs) the following areas are to be covered.

1. **Personnel:** Cleanliness, Education, Training, and Supervision
  - Are ill employees being restricted from work with food when exhibiting symptoms or they have a physician's diagnosis of communicable diseases transmissible through foods?
  - Do supervisory personnel observe workers upon starting work to look for signs of illness or poor personal hygiene? Do supervisors observe employees' hand washing process? Are these observations recorded?
  - Are employees following policies for reporting illness and injury? Are employees provided with written copies and training on policies regarding, injuries, illnesses, personal hygiene and good manufacturing procedures?
  - Are employees clean and properly clothed (*including head and beard covers*) and not wearing jewelry or other items such as cell phones, and calculators that could become physical hazards in the food?
  - Do employee practices such as hand washing and personal hygiene appear to be satisfactory? Can employees demonstrate good hand washing practices during the inspection?
  - Does management have records on performance essential training for employees?
  
2. **Plants and Grounds:** Grounds; Plant Construction and Design
  - Are premises free of harborages and/or breeding places for rodents, insects and other pests?
  - Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests?
  - Is adequate drainage provided to avoid insect breeding areas?
  - Is the building of suitable construction and generally in good physical repair?
  - Are floors, walls and ceilings constructed of easily cleanable materials and kept clean and in good repair?
  - Are processing and storage areas adequately lighted, ventilated, and reasonably free of odors and condensation?
  - Is sufficient space provided for placement of equipment, storage of materials and for production operations?
  - Are food and food contact surfaces protected from contamination from pipes, etc., over working areas?



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 15 of 32

Effective Date:

2-4-14

- Is there adequate separation of food processing and maintenance operations like cutting, welding and grinding? This may be accomplished by physical separation (walls), distance, ventilation or a combination of the three.
  - Are food products and processing areas protected against contamination from breakage of light bulbs and other glass fixtures?
  - Are food-processing areas effectively separated from other operations, which may cause contamination of food being processed?
  - Is air quality and ventilation adequate to prevent contamination by dust, steam and/or other airborne substances? Are vent covers clean?
3. **Sanitary Operations:** General Maintenance; Substances used in Cleaning and Sanitizing; Storage of Toxic Materials; Pest Control; Sanitation of Food Contact Surfaces; and Storage and Handling of Cleaned Portable Equipment and Utensils
- Is the facility kept clean and in good physical repair?
  - Is cleaning of facilities and equipment conducted in such a manner as to avoid contamination of food products?
  - Is condensation controlled to avoid contamination of product?
  - Are all chemicals used in the facility approved for food facilities?
  - Are detergents, sanitizers, hazardous materials and other supplies used in a safe and effective manner?
  - Are cleaning compounds and hazardous materials kept in original containers, properly labeled and stored separate from raw materials?
  - Does the firm have a pest control program and cleaning schedule, which includes routine inspection by qualified personnel?
  - Are the processing areas maintained free of insects, rodents and other pests?
  - Are insecticides and rodenticides used and stored so as to prevent contamination of food?
  - Are all utensils and equipment cleaned and sanitized effectively and at intervals frequent enough to avoid contamination of food products?
  - Are single service articles stored, handled, dispensed, used and disposed of in a manner that prevents contamination?
  - Are multi-use bottles inspected for filth or foreign objects after wash, but prior to fill?
  - Are returned multi-use bottles containing foreign objects or excessive



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 16 of 32

Effective Date:

2-4-14

filth rejected prior to entering the washer?

- If a bulk delivery system is used to receive flour, etc. are hoses and connectors inside and outside of facility clean, in good repair and stored to protect them from contamination?
- Are utensils and portable equipment stored so as to protect them from splash, dust and other contamination?
- Are vehicles used to transport finished product adequate, clean, and in good repair?

4. **Sanitary Facilities and Controls:** Water Supply; Plumbing; Sewage Disposal; Toilet Facilities; Hand washing Facilities; and Rubbish and Offal Disposal

- Is the water supply adequate in quantity and quality for its intended uses? Is it a community system connection or a noncommunity water system?
- Are the water temperatures and pressures maintained at suitable levels for its intended use?
- Are supply lines and hoses for water used as an ingredient or for cleaning food contact surfaces constructed of food-grade material?
- Is the sewage disposal system adequate? Is it a community or an onsite system?
- Is the plumbing adequately sized, designed, installed and maintained in a manner to prevent contamination?
- Are appropriate measures in place to prevent backflow and backsiphonage in the plumbing systems? Inspect plumbing for cross-connections between potable and non-potable water lines. In addition to a backflow prevention device on the incoming water line to the plant, all internal potential cross-connections must be protected, these include: all tanks and vessels including CIP tanks with potable water connections, the "make water" line to cooling towers and chill water systems, boiler feed lines, any location where chemicals are injected or drawn into a potable water line (e.g. plant sanitizer systems or track lube systems), any hose connected to a potable water supply, and irrigation systems.
- Are adequate toilet rooms provided, equipped and maintained clean and in good repair? Are they convenient to the processing area? Are they adequately separated from processing areas?
- Are restrooms provided with proper ventilation?
- Are restroom doors self-closing?
- Are adequate hand washing and/or sanitizing facilities (sanitizing is



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 17 of 32

Effective Date:

2-4-14

used to supplement not replace hand washing) provided where appropriate with hot water, soap and approved sanitary towels?

- Do sinks have hot and cold running water provided?
- Soap, approved hand drying devices and adequate waste receptacles provided at all hand washing sinks?
- Are adequate trash containers provided in restrooms? (Covered containers in women's restrooms).
- Are signs present at the hand washing sinks in restrooms and production areas reminding personnel to wash hands?
- Are adequate facilities for cleaning equipment available and properly used?
- Is all refuse properly stored and protected where necessary from insects, rodents and other pests and disposed of in an adequate manner?
- Are chemicals properly stored to prevent contamination of other products?

5. **Equipment and Utensils:** Easily Cleanable; Thermometers for Freezers and Coolers; Instruments Accurate and Maintained (temperature, pH and water activity); and Compressed Air

- Are all utensils and equipment constructed of adequately cleanable materials and suitable for their intended uses?
- Is the equipment designed and used in a manner that precludes contamination with lubricants, contaminated water, metal fragments, etc.?
- Are seams on food contact surfaces smooth to minimize accumulation of food and dirt (Sanitary welds)?
- Is the equipment installed and maintained so as to facilitate the cleaning of equipment and adjacent areas?
- Are tanks, vats, transfer lines, mixers, and other equipment used for mixing, storage, and transfer of food constructed of smooth, impervious, non-toxic materials that are in good repair?
- Are pumps sanitary pumps, easily disassembled and cleaned?
- Are plastic food storage containers in good condition, without cracks or breaks?
- Is equipment maintained in good repair to facilitate cleaning and assure proper function? This includes being free of cracks, breaks and poor quality welds. Door seals should be in good repair on refrigerators.



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 18 of 32

Effective Date:

2-4-14

- In Beverage plants is bottle washing equipment operating properly with respect to water pressure and temperature, soak time, caustic concentration, mechanical brushing, and rinsing?
  - Are filling and capping operations conducted under satisfactory sanitary conditions?
  - Are bottled beverage production lines operating without apparent excessive glass breakage?
  - Is shelving of proper material and in good repair?
6. **Processing and Controls:** Raw Materials and Other Ingredients; and Manufacturing Operations (45° F for refrigerated foods; 140° F for hot foods)
- Is ice (where used) manufactured from potable water and stored and handled in a sanitary manner?
  - Is food processing conducted in a manner to prevent contamination and minimize harmful microbiological growth? This would include proper processing and holding temperatures.
  - Are raw products properly and adequately separated from cooked products?
  - Are foods and containers of foods properly covered and labeled as required?
  - Are "recondition/rework" and "waste" product properly labeled and segregated from each other?
  - Are chemical, microbiological or extraneous material testing procedures used where necessary to identify sanitation failures or food contamination?
  - Does the firm have a plan for segregation and control of food allergens in the facility?
  - Does the firm have a HACCP plan if appropriate, or other food safety plan in compliance with FSMA requirements?
  - Are packaging processes and materials adequate to prevent contamination?
  - Are only approved food and/or color additives used?
  - Are methods and controls in place to assure prevention of allergen carryover from one product or line to another?
  - Are products coded to enable positive lot identification, and are records maintained in excess of expected shelf life?
  - Are weighing and measuring practices adequate to ensure the declared quantity of contents? Are scales properly certified/tested

	Bureau of Environmental Health Services Manufactured Food Program	
	<b>Inspection Process, Inspection Workflow          and Inventory Maintenance</b>	Page 19 of 32
		Effective Date: <i>2-4-14</i>

when necessary?

- Does post-fill inspection procedure (visual or mechanical) appear to be effective?
- Are finished products stored and shipped under conditions, which will avoid contamination and deterioration?
- Are refrigerators and freezers operating at appropriate temperatures?
- Are refrigerated and frozen products stored at appropriate temperatures (Refrigerated product in storage 45° F, Frozen product in storage 0° F)?
- Are food items loaded in the same vehicle with toxic chemicals or other potential contaminants separated?

**7. Warehousing and Distribution:** Protect against Physical, Chemical, Microbial Contamination; and Protect against Deterioration of the Food and Container

- Are incoming products examined visually for damage or contamination prior to placement in storage?
- Are food products stored off of the floor and away from the walls?
- Does the firm routinely rotate products in storage?
- Are damaged products including spillage removed promptly from the main storage area?
- Does the firm maintain a morgue area for damaged product and returned goods, sufficiently separated from main storage?
- Are cold storage units provided with thermometers and routinely monitored?
- Are products containing any of the eight major allergens properly identified and stored to prevent contamination of other products?

**8. Label Reviews**

- Does the label have the information required by 21 CFR 101?
- Are any exemptions approved for this facility?
- Are labels of products covered during inspection in compliance (submit labels with violations as exhibits)? Are major allergens denoted in some way on the label (either in the ingredients list or a separate allergen statement)?

**B. HACCP Inspections**



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 20 of 32

Effective Date:

2-4-14

NOTE: HACCP Inspections are only to be conducted by inspectors which have completed HACCP training and been approved to do HACCP inspections. Inspectors who have not completed HACCP training are allowed to perform GMP inspections at these facilities. As appropriate for seafood and juice processors subject to HACCP regulations:

Use the *Fish and Fishery Products Hazards and Controls Guide* or the *Juice HACCP Hazards and Controls Guide*, when and as appropriate, to identify and evaluate the hazards associated with the product and process.

FDA's final rule (21 CFR Part 120) requires a processor of juice to evaluate its operations using Hazard Analysis Critical Control Point (HACCP) principles and, if necessary, develop and implement HACCP systems (i.e., a system of preventive control measures based upon HACCP principles) for its operations.

These regulations do not preempt the existing requirements to follow the current Good Manufacturing Practice (CGMP) regulations for your fish or juice processing operations.

The HACCP plan and other records of your sanitation standard operating procedures (SSOPs) and HACCP operations must be available for official inspection and copying.

Employees involved in developing, or in certain aspects of implementing, a HACCP plan, must be trained in HACCP principles.

For juice a 5-log pathogen reduction must be accomplished for the microbe you identify as the "pertinent microorganism," which is the most resistant microorganism of public health significance that is likely to occur in the juice, e.g., *E. coli* O157:H7, must take place in one facility just prior to or after packaging, and be applied directly to the juice, except for citrus juices.

Note: Retail establishments or businesses that make and sell juice directly to consumers and do not sell or distribute juice to other businesses are exempt from the juice HACCP regulation, but must comply with FDA's food labeling regulation in 21 CFR 101.17(g) that requires a warning statement on packaged fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present, and with any applicable state regulations.

When performing a HACCP inspection, the following areas should be assessed:

- Is a Hazard Analysis Critical Control Point (HACCP) plan required?

	Bureau of Environmental Health Services Manufactured Food Program	
	<b>Inspection Process, Inspection Workflow          and Inventory Maintenance</b>	Page 21 of 32
		Effective Date: <i>2-4-14</i>

- Is required HACCP plan available for review? When was the HACCP plan last reviewed and updated?
- Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation.
- Review the firm's HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring verification and corrective action records, including those related to sanitation.
- Recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations
- Are flowcharts, hazard analyses, monitoring logs, corrective action documentation and verification records available for review?
- Are pest control logs and cleaning schedules available for review?
- Is documentation of employee training maintained?
- FDA's final regulations (21 CFR Part 123) that require processors of fish and fishery products to develop and implement Hazard Analysis Critical Control Point (HACCP) systems for their operations. Those final regulations were published in the Federal Register on December 18, 1995 and became effective on December 18, 1997.

### C. Reconciliation Exams

Reconciliation exams are performed to ensure that a firm can track any shipment of ingredients through the manufacturing process and identify the finished products the ingredients were used in. The process of tracking ingredients can become exponentially more difficult when a facility has a rework process. A firm's ability to identify which ingredients went into a product is extremely important when performing traceback investigations of foodborne illnesses tied to a specific food ingredient.

To perform a reconciliation exam look at a bill of lading and identify an ingredient which has been used (or partially used) in the manufacturing process. Ask if the firm can tell you which finished products the ingredients went into. If an acceptable response is received, document that the reconciliation exam was performed on ingredient "x" and that the firm was able to identify which specific finished products this ingredient was used to manufacture. If the firm "fails" their reconciliation do not document as a violation. A note should be added on the inspection report that states "reconciliation examination was performed for ingredient "x" and the firm was not able to identify which specific finished products this ingredient was used to manufacture. A record keeping system should be implemented to achieve this capability".



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 22 of 32

Effective Date:

2-4-14

This process only applies to food manufacturers. There is no need to attempt a reconciliation examination in a warehouse.

**XI. Evidence Collection**

The recognition, collection, and effective presentation of admissible evidence is essential to successful litigation. Tangible evidence is required to support your observations and reports of violative conditions.

Evidence Examples:

- Samples of raw materials or finished products collected during inspections provide the necessary key to establish routes of contamination. They also document the character of products packed prior to the inspection. These samples are often only done when requested for enforcement or investigative purposes.
- Impressive exhibits are extremely effective and important forms of evidence to establish existence of violative conditions or products. They should relate to insanitary conditions contributing or likely to contribute, filth to the finished product, or to practices likely to render the product injurious or otherwise violative. Diagrams of the establishment, floor plans, flow charts, and schematics are useful in preparing a clear concise report and in later presentation of testimony. A small compass is useful in describing exact locations of objectionable conditions in the plant, in your diagrams, and locations from which samples were taken, etc.
- Live and dead insects. Insect frass, webbing, and insect chewed materials; nesting material of rodents and/or other animals; and other behavioral evidence of the presence of insects, rodents and other animals.
- Physical samples if possible and practical or, photographs with descriptions of scoops, stopgap expediciencies, other unorthodox manufacturing equipment or makeshift procedures.

Photographs are one of the most effective and useful forms of evidence, each should be taken with a purpose. Photographs should be related to insanitary conditions contributing or likely to contribute filth to the finished product, or to practices likely to render it injurious or otherwise demonstrate violations.

	Bureau of Environmental Health Services Manufactured Food Program	
	<b>Inspection Process, Inspection Workflow          and Inventory Maintenance</b>	Page 23 of 32
		Effective Date: <i>2-4-14</i>

CAUTION: Evaluate the area where flash photography is contemplated. Do not use flash where there is a potentially explosive condition; e.g. very dusty areas or possible presence of explosive or flammable vapors. In this situations use camera settings to increase exposure of the picture (higher ISO or slower shutter speed) instead of flash.

Examples of conditions or practices effectively documented by photographs include:

- Evidence of rodents or insect infestation and faulty construction or maintenance, which contributes to these conditions.
- Routes of, as well as, actual contamination of raw materials or finished products.
- Condition of raw materials or finished products.
- Employee practices contributing to contamination or to violative conditions.
- Manufacturing and various control records showing errors, substitutions, penciled changes in procedure, faulty practices, deviations from GMPs, or other protocols, altered or inadequate assays or other control procedures and any variation from stated procedure.
- Effluent contamination of water systems.

When photographing labels, make sure your picture will result in a legible label with printing large enough to be read by an unaided eye.

Do not request permission from management to take photographs during an inspection. Take your camera into the firm and use it as necessary just as you use other inspectional equipment.

*If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of plant conditions. Advise management the U. S. Courts have held that photographs may lawfully be taken as part of an inspection. If management continues to refuse, provide them with the following references:*

*"Dow Chemical v. United States, 476 U.S. 227 (1986) This Supreme Court Decision dealt with aerial photographs by EPA, but the Court's language seems to address the right to take photographs by any regulatory agency. The decision reads in part, "\*\*\* When Congress invests an agency with enforcement and investigatory authority, it is not necessary to identify explicitly each and every technique that may be used in the course of executing the statutory mission. \*\*\*\*"*  
*"United States of America v. Acri Wholesale Grocery Company, A Corporation, and JOSEPH D. ACRI and ANTHONY ACRI, Individuals", U.S. District Court for Southern District of Iowa. 409 F. Supp. 529. Decided February 24, 1976.*



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 24 of 32

Effective Date:

2-4-14

If management refuses, advise your supervisor so legal remedies may be sought to allow you to take photographs, if appropriate. If you have already taken some photos do not surrender film to management. Advise the firm it can obtain copies of the photos under the Freedom of Information Act.

One of the most critical aspects about photographs or videotapes is the ability for the agency to provide testimony clearly verifying the authenticity of the conditions depicted in the photograph or video. You must create a trail, starting with the taking of the photo, confirming its original accuracy and establishing a record describing the chain of custody. To do this, you must make sure each photograph is described in your notes in sufficient detail to assure positive correlation of the photo or video with your inspection findings. You are responsible for collection, handling, documenting the chain of custody, storage, and submission of your evidence in a manner where you can testify to its authenticity in a court of law. See IOM 5.3.4.2 and 5.3.4.3.

## XII. Documentation of Violations

Proper documentation of violations conditions includes:

- Stating the violation.
- Noting the location(s) in the facility where the violation occurs.
- Where appropriate a possible corrective action.
- Document the regulatory reference for the violation, i.e. 110.10(b)(1)
- A specific correction time frame if a re-inspection is required by policy.

When noting violations on the inspection report form, be sure to write observations not conclusions. Example: "Cockroaches were found on the wall west of the pan washer" or "the warehouse has excessive cobwebs at the wall ceiling juncture." Do not write, "the facility must be free of pests" or "clean the warehouse," as these are conclusions or directions and do not specify the violation as seen during the inspection. Write the narrative as if outsider layman was going to read it and had to determine the violation you observed. When providing recommendations for compliance, place them after your observation, i.e. "The agitator seal is missing on batch processor number six. Equipment must be designed and maintained to protect food from contamination, replace the missing seal."

When appropriate the investigator can provide a brief description of manufacturing processes and controls for product(s) inspected. Where appropriate report times, temperatures, and other critical processing steps should be noted. Copies of labels, forms, flow charts and other relevant data may be attached to better clarify the written documentation of the report. After discussing the inspection report and recording all comments or requested corrective actions on the inspection report form, obtain the signature of the



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 25 of 32

Effective Date:

2-4-14

owner, manager, or responsible person in charge. If necessary, explain that by signing the report, the individual is acknowledging only the receipt of the inspection report. Give one copy to the owner/manager/person in charge and suggest the report be posted in the establishment or maintained in a file on premises. Document in notes the responsible individual's responses to any violations noted, corrective actions taken at the time of observation, and corrective actions agreed to by the owner/manager/person in charge.

DHSS and its representatives must strive for correctness and consistency in exercising the recognition and correction of violations observed during an inspection of a processing facility. Significant insanitary conditions or violations noted during an inspection require correction within a specific time frame. The timeframe should be appropriate for the violation.

**XIII. Adulterated food**

Circumstances may be present where there are adulterated foods that must be removed from the human food chain but the facility as a whole does not constitute an imminent health hazard. An example would be condensation dripping on ready to eat produce. If there is a relatively small quantity of food that will be disposed of immediately, witness the destruction of the food and make note of this fact on the inspection report. If a large volume of food is involved, embargo the food and make arrangements to witness or otherwise assure it is destroyed or removed from the human food supply.

**XIV. Imminent Health Hazards**

The severity of the violations noted during a routine inspection may cause the investigator to take additional steps to assure timely correction. Conditions which constitute an immediate threat to health and safety or blatant disregard for public safety are considered imminent health hazards and may be grounds for requesting a closing order. Conditions that would require immediate action to correct and subsequent follow-up would include conditions such as:

- Substantiated link to an ongoing Food borne Illness Outbreak.
- No potable water to the facility.
- No refrigerator or freezer storage available for products that require them.
- Sewage back-up in the processing/storage facility.
- Unsanitary conditions throughout the facility.
- Evidence of current product adulteration.
- Distressed or damage product requiring destruction.
- Power outage, fire, flooding.
- Response to a recalled product notification.
- A rodent or insect infestation such that food could not be produced in the facility without a likelihood of adulteration.



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 26 of 32

Effective Date:

2-4-14

**XV. Follow-Up Inspections**

Follow-up or re-inspections are scheduled when an inspector notes violations of public health significance that cannot be corrected while on-site. When determining the date for follow-up, the inspector should consider the number of violations as well as the severity of the violations. This date for the follow-up inspection should be discussed with the establishment manager at the time of the routine inspection and is normally set for 7 to 14 days. It is imperative that reinspections be conducted on the date scheduled. During reinspections only check the violations noted from the routine inspection. However, if when conducting a reinspection you determine facility conditions have deteriorated since the original inspection and a number of new significant violations are found, do not complete the reinspection- instead complete the inspection as a routine inspection and schedule another reinspection. Violations not noted on the preceding routine inspection should not be noted on a reinspection.

Violations requiring a re-inspection would include conditions such as:

- Pest infestation.
- Lack of hot water.
- Major or numerous sanitation issues.
- Temperature control issues.
- Personnel with infection.
- Unapproved sources for ingredients or water.
- Serious protection from contamination violations.
- A lack of handwashing.

Violations that would require correction by the next routine inspection could include conditions such as:

- Screen repair for window or doors
- Labeling issues not related to Allergens
- Lack of FDA registration.
- Surfaces in disrepair
- Unlabeled spray bottle(s)
- Improper concentrations of sanitizers.

**XVI. Exit Interview**

Before leaving the facility the investigator will discuss the contents of the inspection report form, including all violations noted on the form, with owner/manager or person-in-charge. NOTE: it is important to explain the observations cited rather than just reading them to the firm. If correction

	Bureau of Environmental Health Services Manufactured Food Program	
	<b>Inspection Process, Inspection Workflow          and Inventory Maintenance</b>	Page 27 of 32
		Effective Date: <i>2-4-14</i>

timeframes are needed the investigator and management will come to agreement as to length of time needed and when a follow up inspection will be conducted. The correction time frames will be written on the inspection form (even if no follow up inspection is planned). The investigator will allow time for answering questions from management and instruct them on how to contact the investigator again if further discussion is required before corrections are made. The inspection report form will be signed as being received by a representative of the firm. The original copy of the form will be left with the firm. Some firms will not allow employees to sign the inspection report form. In these cases make a note and include who the report was issued to. For example: "Company policy prohibits signature. Issued to Joe Smith, Plant Manager 1/1/13." In these circumstances inform the individual receiving the inspection report that a copy of the inspection report will be sent to the firm's corporate headquarters by certified mail.

**XVII. Food Product Traceback**

One of the important roles of public health and the manufactured food program is to end ongoing foodborne illness outbreaks as quickly as possible. To this end, knowing that individuals eating cantaloupe from XYZ farm in Colorado are contracting listeriosis is far better information than just knowing that individuals eating cantaloupe are getting sick. Identifying the specific food involved in an outbreak is the primary role of a traceback.

For specific instructions on conducting a product traceback please review the following documents:

O:\EHS\Manufactured Food\Policies and Procedures\Supporting documents\Foodborne Illness Traceback.pdf

O:\EHS\Manufactured Food\Policies and Procedures\Supporting documents\FDA produce traceback guide.docx

A product traceback will not be conducted for every foodborne illness outbreak. If salad at a restaurant is associated with a norovirus outbreak and an environmental assessment of the restaurant finds the person who prepped the salad was experiencing the symptoms of norovirus, there is likely no value or benefit of doing a traceback to determine which farm in California produced the lettuce in the salad. The decision to perform a product traceback will be made based on the strength of the epidemiologic data and a host of other factors. These can be difficult decisions; as such the food program managers and bureau chief will be involved in the process.



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 28 of 32

Effective Date:

2-4-14

Most often any traceback we are involved in will involve foods where we and FDA have the primary regulatory authority, other times we may participate in the traceback of cosmetics, drugs, medical devices or USDA food items.

A traceback can be extremely complex or extremely simple for example; epidemiologic data may implicate a manufactured food is the likely source of an outbreak, a call to the company reveals that all of that particular product is made at their Henderson Nevada plant and that according to the lot codes the specific jar of product in question was filled at 10:04 AM on October 8th 2013. On the other hand, a traceback of tomatoes may reveal that they have passed through six distributors from the farm on the way to the grocer, lots may have been comingled and records may be incomplete. It can take reams of data and many man-hours of analysis to sort out where the specific tomatoes associated with an outbreak originated.

It is very important that when we conduct a traceback that our records and documentation be thorough and orderly. These records should be retained for a minimum of five years.

Occasionally the entire distribution path of a product may all be in the state of Missouri, more often we may be investigating a multistate outbreak and our traceback information is funneled to FDA as part of a larger traceback. Often in these instances we coordinate and work with our counterparts in FDA. If the results of a traceback indicate product originated in a Missouri manufacturing firm or on a Missouri farm, a thorough investigation will be conducted to establish a root cause of the problem and assist with development of preventative measures to avoid future incidents.

## XVIII. Inventory of Firms

### C. Inventory Maintenance

- Inspectors will notify Administrative Support of any new firms or any that have gone out of business (with or without a contract inspection).
- Administrative Support will:
  - Email the list to inspectors twice a year (January and June) and update the Inventory of Firms List accordingly with results from inspectors.
  - Add information to the database on any new firm.
  - Change the status in the database to OOB or Not OEI if a firm no longer produces manufactured foods.

	Bureau of Environmental Health Services Manufactured Food Program	
	<b>Inspection Process, Inspection Workflow          and Inventory Maintenance</b>	Page 29 of 32
		Effective Date: <i>2-4-14</i>

- Update the Inventory of Firms from the Inspection Report Form and/or eSAF report submitted by the inspector or emailed by FDA Program Manager.
- Maintain file folder for each firm in the inventory and include inspection reports and eSAF forms in the file.

### **XIX. Industry Complaints About Inspections**

Industry complaints received about an inspection will be forwarded to the Program Manager. The Program Manager will determine if the complaint is in regard to disagreement with a regulation, lack of supporting regulation, a difference in opinion with regard to an inspection finding, or another issue.

If the complainant disagrees with an inspection finding that is supported by State and/or Federal Regulation then the Program Manager will discuss where the complainant can find the regulation supporting the finding and why compliance is important/required.

If the complainant disagrees with an inspection finding and the Program Manager determines that the inspection finding is not supported by State or Federal Regulation then the Program Manager will:

- Work with the inspector's supervisor to discuss the finding with the inspector who performed the inspection and explain why the regulations do not support the finding.
- Follow up with the complainant that a correction is not required for the finding.

If the complainant disagrees with an inspection finding and there is a difference of opinion between the inspector and the complainant as to whether the finding is a violation to a regulation, the Program Manager or designated Auditor will:

1. Discuss the finding with the inspector and the complainant.
2. If warranted, visit the facility to observe the issue.
3. Provide the final decision as to whether the finding is a regulatory violation.
4. Follow up with the complainant with regard to the decision.
5. Industry complaints about inspections are to be documented and kept in the file for that facility.



Bureau of Environmental Health Services  
Manufactured Food Program

Inspection Process, Inspection Workflow  
and Inventory Maintenance

Page 30 of 32

Effective Date:

2-4-14

## XX. Industry Complaints About Inspectors

If the owner or management of a manufactured food facility brings allegations against a DHSS inspector involving one of the following:

- **Assault:** An act that results in bodily harm or willful attempt to inflict bodily harm.
- **Harassment:** An act or behavior to annoy or torment repeatedly and persistently.
- **Intimidation.** An act or behavior to compel or deter action by coercion, extortion, duress, or threat.
- **Retaliation.** An activity perceived as an action to get even or to control a particular situation or business relationship.
- **Threat.** Any gesture or verbal or written expression that conveys intent to cause physical or non-physical harm to the individuals or their property.

It is the program's policy to:

1. Utilize senior staff to conduct a complete and thorough investigation into all complaints against program employees by industry officials.
2. Seek prompt resolution of complaints against program employees by industry officials.
3. Ensure all parties receive information on the results of the inquiry, as appropriate.

Complaints of this nature must be formal complaints and be submitted in writing and contain the following:

- (1) Name of complainant.
- (2) Name of BEHS employee(s).
- (3) Statement explaining the nature and scope of the incident(s) including date(s), time(s), and names of witnesses.
- (4) Explanation of prior attempts to resolve the complaint, if applicable.

Disposition of these complaints, including possible personnel or disciplinary actions will be made in accordance with Department policy.

## XXI. Record Retention

Inspection reports and records pertaining to followup activities and complaints about inspections will be maintained for a minimum of three years or per state policy.



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES  
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

**FOOD PROCESSOR PUBLIC HEALTH PRIORITY ASSESSMENT WORKSHEET**

FDA FEI (if applicable)		ESTABLISHMENT NAME	
ADDRESS			ZIP CODE
<p>Firms where any of the following conditions are present are automatically identified as a high risk/high priority establishment:</p> <ul style="list-style-type: none"> <li>a. Enforcement actions - Previous confirmed involvement in foodborne illness or previous Closing Order issued, significant destruction of product necessary, significant sanitation concerns.</li> <li>b. Products which carry a high risk of illness (Cereal, bottled beverages, juices, sprouts, sandwiches, seafood and RTE processed produce).</li> <li>c. Complex processes, including acidified, naturally acid or low acid canned foods, retorted foods, vacuum packaging, multiple steps of cooking and cooling potentially hazardous foods.</li> <li>d. Firms with no inspection history.</li> </ul> <p>If the above conditions are not applicable to the firm use the following criteria to evaluate risk/priority. NOTE: Assessments are to be performed in conjunction with an inspection.</p>			Automatically High Priority Establishment
1. Firm Size			
<ul style="list-style-type: none"> <li>a. &gt; or = 7</li> <li>b. 4-6</li> <li>c. &lt;4</li> </ul>		<ul style="list-style-type: none"> <li>a. 1.5</li> <li>b. 1.0</li> <li>c. .5</li> </ul>	
2. Past History			
<ul style="list-style-type: none"> <li>a. Repeated sanitation concerns, previous voluntary destruction of some product, inability to demonstrate understanding of GMPs or food safety, establishments requiring follow-up inspections</li> <li>b. No adverse observations or minor sanitation violations, no follow-up inspection(s) required, sanitation concerns not repeated</li> </ul>		<ul style="list-style-type: none"> <li>a. 1.0</li> <li>a. .5</li> </ul>	
3. Products:			
<ul style="list-style-type: none"> <li>a. Products with multiple ingredients, one or more potentially hazardous ingredients and/or involving allergen ingredients (e.g. baked goods, colorants, flavorings, chocolates)</li> <li>b. Single-ingredient products, warehouses -including refrigerated/frozen warehouses. (e.g. honey, coffee)</li> </ul>		<ul style="list-style-type: none"> <li>a. 1.0</li> <li>b. .5</li> </ul>	
4. Processes:			
<ul style="list-style-type: none"> <li>a. Moderately complex processes, including mixing/blending, adding or removing moisture, cooking and/or cooling of foods.</li> <li>b. Simple processes (e.g. grinding, freezing, packaging or repackaging, storage of packaged product)</li> </ul>		<ul style="list-style-type: none"> <li>a. 1.0</li> <li>b. .5</li> </ul>	
<p>Total Points _____ divide by 4 = _____</p> <p>Public Health Priority if: (&gt;1.1) HIGH (.9-1.1) MEDIUM (&lt;.9) LOW</p>			
<p>Assessed priority category: _____</p> <p>Date of assessment: _____</p> <p>Assessed by: _____</p>			



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES  
BUREAU OF ENVIRONMENTAL HEALTH SERVICES

INSTRUCTIONS ON COMPLETION OF RISK ASSESSMENT FORM

1. Firm size is based on the following categories set by the FDA. These amounts represent gross annual sales of the facility. Select the proper category and circle on the form.

<u>CODE</u>	<u>SIZE</u>
0	\$ 0 - \$ 24,999
1	25,000 - 49,999
2	50,000 - 99,999
3	100,000 - 499,999
4	500,000 - 999,999
5	1,000,000 - 4,999,999
6	5,000,000 - 9,999,999
7	10,000,000 - 24,999,999
8	25,000,000 - 49,999,999
9	50,000,000 and over

2. Past history follows the explanations on the form.
3. Products follow the explanations on the form. An appropriate evaluation will consider/include all items produced or handled in the facility, so an evaluation will be completed each year if items have been added or if any have been removed from production/distribution since the last inspection. Having a copy of the previous inspection information should help to assure you haven't missed anything. The FDA information on products covered on previous inspections can be helpful if it is available.
4. Processes use the details on the form. Process complexity can be determined by having a step-by-step explanation of the production of the items made at the facility. If the firm has third party inspections or are required to have a HACCP plan, those tools can provide more details of how the items are produced at each site.
5. Apply the risk factor categories on the form, total the points from each risk factor category evaluation, divide by the number of risk factors (3 or 4), assign the appropriate risk priority (High, Medium, or Low) based on those results.
6. Required inspection frequencies for the categories are as follows:
  - a. High Risk inspected at least every 12 months
  - b. Medium Risk inspected at least every 24 months
  - c. Low Risk inspected at least every 36 months