Minnesota Department of Agriculture
Food and Feed Safety Division

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1. PURPOSE

This document describes the procedure for conducting and documenting FDA Food Contract Inspections within the Minnesota Department of Agriculture (MDA) Food and Feed Safety Division (FFSD).

2. SCOPE

This document will be used by all inspectors when conducting FDA Food Contract Inspections. This procedure does not apply to routine inspections at food retail facilities, manufacturing facilities, or investigations.

3. BACKGROUND

States play a critical role in overseeing the nation's food supply. State and local governments conduct the majority of inspections in the U.S., including food retailers, manufacturers, processors and distributors within State boundaries. Many of the food firms inspected by States may also fall under Federal jurisdiction if they are involved in interstate commerce. State food inspectors are generally in the field more frequently than FDA food inspectors and offer an important source of front-line experience and expertise.

Minnesota currently has a contract with the FDA to conduct inspections of food establishments to determine compliance with the food provisions of the Federal FD&C Act and State laws. To meet the obligations of the contract, FFSD Food inspectors must conduct inspections in accordance with this procedure and submit proper documentation. Through this work, Minnesota and the FDA will continue to support an integrated food safety system.

4. RESPONSIBILITY

Manufactured Food Program Manager – The Manufactured Food Program Manager will assist inspectors or supervisors with questions related to FDA Contract Inspections and communicate with the FDA as needed.

Manufactured Food Supervisor - The Supervisor will assist the inspector in making Visit determinations and communicate with the FDA as needed.

Manufactured Food Inspector – The Inspector will conduct the FDA Contract Inspection, complete the FICS and MDA Inspection Report, and submit all documentation for the inspection following the procedures.

5. DEFINITIONS

Assigned Inspection Types: An Assigned Inspection type is an assignment made when the FDA contract is entered into eSAF that designates the focus of the inspection for the current contract year. Inspection types may include: GMP, Seafood HACCP, Juice HACCP, Low Acid Canned Food/ Acidified Food (LACF/AF), and/or Audit.

Corporation: A corporation is a separate legal entity that has been incorporated through a registration process established through legislation. This includes the following types: General Corporation, S Corporation, and Limited Liability Company (LLC).

Electronic State Access to FACTS (eSAF): eSAF is an electronic, online portal that allows state access to FACTS, the Field Accomplishment and Compliance Tracking System utilized by FDA. State contract inspections are assigned, completed, and submitted in the eSAF system.

FDA Jurisdiction: FDA jurisdiction means products or ingredients not covered by USDA (*Appendix B – Amenable and Non-Amenable Food Items*), and entering into or received via interstate commerce e.g. from a country, state, or territory other than Minnesota.

FDA Inspection Contract Summary (FICS): A FICS is a report prepared by MDA when a FDA Food Contract Inspection is conducted to document specific information gathered and to summarize inspectional findings and results. The report is provided to FDA (MIN-DO) as documentation of the work conducted during the inspection. The form is to be used for all GMP manufacturing, Seafood HACCP, Juice HACCP, LACF/AF, and Environmental Sampling Inspections except when the FICS-Visit or FICS - Warehouse form applies.

FDA Inspection Contract Summary (FICS) – Visit: A FICS-Visit is a report prepared to document specific information gathered when and FDA Contract Visit is conducted.

FDA Inspection Contract Summary (FICS) – Warehouse: A FICS-Warehouse is a report prepared when an FDA Food Contract Inspection is conducted to document specific information gathered and summarize inspectional findings and results. The report is provided to FDA (MIN-DO) as documentation of the work conducted during the inspection. The form is to be used for all warehouse GMP Inspections EXCEPT that when a warehouse is subject to the Seafood HACCP regulation (21 CFR 123), the main FICS must be completed.

FDA OOB: FDA OOB is a firm that is no longer operational and has closed; no activity. This does not include firms that have moved to another address.

MDA OOB: MDA OOB means a discontinued operation or a change of ownership at a specific physical location in Minnesota. This includes firms that have moved to another location or still operate outside of Minnesota.

No Action Indicated (NAI): NAI is an inspection conclusion/classification for no significant violations or violative conditions found during the inspection that closely link to public health risk and/or product adulteration (Refer to FOOD.30.01 Inspection Protocol –Food Manufacturing Section 6.4. 8 & 9).

Product Code and Description: Product codes are classifications used by FDA for individual food product types. They are created using the product code builder tool found online and generate a product description that must be entered with the code on the FICS form. At least one product code must be entered for each FDA contract inspection conducted, with the exception of visits done under contract. The FDA product code is seven characters long and is broken into the following segments: industry, class, subclass, process identification code, and product.

Specialized Process: Specialized process includes Seafood HACCP (21 CFR 123), Juice HACCP (21 CFR 120), Low Acid Canned Foods (21 CFR 113), and Acidified Foods (21 CFR 114). (These processes have additional regulations that apply and requires that the assigned inspector complete special training beyond GMP training in order to conduct that type of inspection.)

State Action Indicated (SAI): SAI means an inspection conclusion/classification for significant violations found and documented warranting some type of regulatory action be taken by MDA. See guidance in *FOOD.30.02 - Reinspection SOP*, for reinspection criteria, which are an indicator of an SAI classification. (MDA Supervisor notifies the FDA State Liaison within three working days regarding the violations and type of follow-up action proposed by MDA.)

Violative: Violative means a product or condition that does not comply with applicable regulations enforced by the MDA. This can be applied to an activity, process, product, equipment or facility used by a firm in the handling of food.

Visit: A visit means an inspection was attempted and the establishment was found to be FDA OOB, MDA OOB, not an official establishment (NOE) as defined by FDA, not subject to coverage under the food contract (i.e. retail only or products subject to FDA jurisdiction but not food, such as drugs or cosmetics), relocated outside of the State of Minnesota, or when a complete inspection cannot be accomplished during the contract period of performance for unforeseen circumstances. Perform all reasonable efforts to locate firms that have moved or relocated.

Voluntary Action Indicated (VAI): VAI means an inspection conclusion/classification for significant violations or violative conditions found and documented during the inspection. (Refer to the applicable sections of *FOOD.30.01 - Inspection Protocol –Food Manufacturing*).

6. PROCEDURES

6.1. Inspection Preparation

6.1.1. Access the eSAF Form in the SharePoint Document Set and review for the following information:

a. Firm assigned address
b. Product List
c. Endorsement including: historical information about the firm, previous inspection scope (feed vs. food, warehouse vs. manufacturing), previous inspection classification, and objectionable conditions.
d. Registration Status.

6.1.2. Evaluate the following files:

a. FDA conducted inspections for the assigned facility (if available) on the SharePoint Food Contract Site. Review using the same information listed under 6.1.1 with the addition of processes.

b. Last MDA-FDA Contract Inspection (found in inspectors files or FDA Contract SharePoint site)

c. MDA inspection files (hard copy or USAFS) including but not limited to: inspection report, sample results, enforcement actions, and other historical documents

6.1.3. Conduct an internet search of the firm if unfamiliar or if it has not been inspected by MDA or FDA to identify:

a. Additional information on product line and process;

b. Location changes or verification of current address.

6.1.4. Review current FDA handouts and the FICS.

6.1.5. Look up the firm's registration status in the FDA FURLS system: https://www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1

Each inspector is responsible for doing this for every assigned inspection. Permissions must be granted by FDA to access this system. Contact your supervisor or program manager for instructions on how to create an account in the FURLS system.

6.1.6. Review field inspection audit form and other resources if the inspection is assigned as an audit.

6.2. Evaluate the assigned inspection type

6.2.1. Confirm that the facility is assigned the correct inspection type. If a firm is assigned as a GMP inspection but conducts a specialized process, notify the supervisor to determine if a specialized process inspection could be assigned.

6.2.2. If a firm assigned as a specialized inspection cannot be completed as such (i.e. the firm does not produce the specialized product), follow the steps below:

a. Notify supervisor immediately of the change.

b. Request approval to change the assigned inspection type and conduct inspection as a normal GMP inspection. Document changes in the summary section of the FICS. Example: This inspection was originally assigned as a Seafood HACCP inspection; however the firm no longer handles any products subject to 21CFR123.

6.3. Visit Determination

6.3.1. If a firm appears to be out of business (OOB), identify if it is MDA OOB or FDA OOB. Use the following techniques below to research if the firm is OOB (Quality Assurance staff may be able to assist with research for a firm):

a. Conduct a site visit (must be done for every Visit);

b. Call the contact phone number;

c. Ask neighbors or contact the post office;

d. Conduct an internet search for the firm name and address.

e. If it is determined that the firm has moved to a new location out of state, collect as much information as possible about the new location (specific address, city, State)

6.3.2. Document all steps taken to identify if the firm is OOB in the FICS-Visit. Include dates, the names and title of the people spoken with regarding the firm's operations or business status, describe what currently occurring at the assigned location (i.e. space is vacant with 'For Sale' sign, space now occupied by Quality Auto Parts).

6.3.3. Use the table below to determine the type of visit and the appropriate course of action when a firm is determined to be a visit:

Situation	**Type of Visit**	**Steps**
Firm has moved within Minnesota. Another food firm is or is not operating in that location.	MDA OOB	1. Contact Supervisor and provide information and new location (if applicable). 2. Await direction from Supervisor.
Firm moved outside of Minnesota. No other food firm is operating at the assigned location.	MDA OOB	1. Notify Supervisor regarding change. 2. Complete FICS-Visit. 3. Mark Not Operating in Minnesota as the classification.
Firm moved outside of Minnesota. Another food firm is operating at the assigned location.	MDA OOB	1. Contact Supervisor and provide information and new location (if applicable). 2. Await direction from Supervisor.
No operating location can be identified and no other food firm is operating at the assigned facility.	MDA OOB and FDA OOB	1. Notify Supervisor regarding change. 2. Complete FICS-Visit. 3. Mark OOB as the classification
If the firm does not engage in activities or manipulate products subject to FDA jurisdiction but is still selling food (such as only products under USDA-FSIS inspection) OR the firms is still operational but has operations outside of FDA jurisdiction	Not Official Establishment (NOE)	1. Notify Supervisor regarding change. 2. Complete FICS-Visit. 3. Mark NOE as the classification. 4. Document steps taken including name and title of all persons spoken with regarding the firm.
If a firm handles products subject to FDA Jurisdiction but is not Food such as Drugs or Cosmetics.	Other	1. Notify Supervisor regarding change. 2. Complete FICS-Visit. 3. Mark Other as the classification. 4. Document steps taken including name and title of all persons spoken with regarding the firm.
If the firm handles food but ONLY has retail sales (no wholesale).	Other-Retail Sales only	1. Notify Supervisor regarding change. 2. Complete FICS-Visit. 3. Mark Other – Retail Sales Only as the classification.

6.3.4. Consult with a Supervisor for additional clarification for the appropriate Visit determination. The Supervisor may need to contact FDA to determine next steps and/or if completion as a Visit is appropriate

a. A contract inspection of the firm at a new location in Minnesota may be reassigned if it is in a different territory.
b. Supervisor may advise to conduct just the MDA inspection (license firm at new location or a new firm at the assigned location).

6.3.5. Log time spent researching information about the firm as hours on the FICS-Visit.

6.3.6. Do not create a new facility in USAFS if:

a. a firm is Out of Business (resulting in a Visit), and does not exist in USAFS because it was previously placed OOB in LIS, Tracking or USAFS; or
b. is NOE because the firm does not handle FOOD AND a NOI is not issued, and there is no inspection conducted.

6.4. Conduct the Inspection

6.4.1. State that you are conducting an FDA Contracted inspection and the inspection is conducted under state authority when issuing the Notice of Inspection.

6.4.2. Conduct inspections when the firm is operational and in production when at all possible.

a. If the firm is not producing at the start of the inspection but will produce later that day or the following day, you should continue the inspection to observe the processing operations.

b. Inspections of high risk firms, especially those that conduct specialized processes, must be conducted when they are operational and in production.

c. Exceptions must be approved by MIN-DO and may include small firms that produce infrequently or firms whose products or process present a low risk. Contact a supervisor for an exception approval.

6.4.3. Establish FDA jurisdiction by verifying products or ingredients enter into or are received via interstate commerce e.g. from a country, state, or territory other than Minnesota.

a. Interstate commerce is to be established on product involved in the current day's production. If this is not possible, establish interstate commerce based on the firms biggest selling item.

b. This information can be verified by
   i. a transportation record document,
   ii. examination of finished products or ingredients and their associated label
   iii. An invoice alone is not sufficient evidence of interstate commerce.

iv. Discussion with the MRP. If this is how interstate commerce is determined and it is a violative inspection, then an affidavit must be completed. Refer to Affidavit Work Instruction.

c. Document the product, address, and name of supplier or customer on the FDA Contract Inspection Template.

6.4.4. Follow all applicable Food and Feed Safety Division SOPs for completing a manufactured food or warehouse inspection.

6.4.5. Obtain appropriate information to complete the FICS throughout the inspection. Information can be gathered using the following techniques: interviewing staff, direct observations, record review, etc.

6.4.6. Do not provide contract inspection information including the FICS, evidence collected, or other supporting documentation to the firm. An exception is photographs collected of environmental sample sites and *Environmental Sample Collection Record*. All information collected as part of the contract inspection and to complete the FICS is confidential and belongs to FDA. If there are further questions, contact your supervisor.

6.4.7. When potentially violative products identified, take the following steps:

a. Identify and document specific food products affected (suspected or clearly identified as violative). Obtain documentation of interstate commerce related to the violative product or process.

b. Determine and relate the specific observed condition to the food product or process being conducted through a narrative description, photos, sample collection, or other documents such as records.

c. Contact a supervisor to determine what additional evidence or information needs to be collected.

6.4.8. Samples may be collected for analysis and paid under the FDA contract; consult the current years *FDA Contract Sampling Work Plan* to determine samples that may be applicable.

6.5. Complete the MDA Inspection Report

6.5.1. Complete a MDA Inspection report for all FDA Contract Inspections (including Visits), except as noted in 6.3.6.

6.5.2. Refer to the USA Food Safety (USAFS) Guidance documents and the *FOOD.30.05 - Inspection Report Writing SOP* along with the specifics listed below for FDA Contract Inspections when completing the MDA inspection report.

<u>For USAFS completed reports or paper reports, complete the following:</u>

a. In the published comments or comments section, add the following:
   i. Standard comment language stating that this inspection was conducted under contract with FDA.
   ii. Listing of the FDA resources that were provided to the firm

Do not include any additional comments about information or evidence collected only because of the FDA Contract inspection. Examples of FDA Data that must not be included are:

- Statements regarding FDA registration including status, number, etc.
- Establishment of FDA jurisdiction/interstate commerce, administrative data, firm information history, and maintenance of records required under the BT Act.
- Names of suppliers or customers.

Specific to USAFS completed reports:

b. Check the box that says *FDA Contract Inspection?*
c. Document the firms' FEI number on the Facility page

6.5.3. Include the following in all documentation (violative or non-violative):

a. Narrative with accurate, detailed, and objective observations. Do not make inferences, assumptions, and judgments.

b. If a product or process was not directly observed, document any statements about the product/process including who made the statement, and their title/position of authority.

c. Ask follow-up or clarifying questions to ensure understanding of information being provided by the firm.

6.6. Complete the FICS: General Comments

6.6.1. Complete all sections as a narrative using proper sentence structure, correct spelling, and punctuation. Ensure that the report is detailed, logical, correct, and professional.

6.6.2. Use the FICS as a template. The narrative sections may be modified to better represent the inspection and the firm's information. However, do not modify the table format and do not eliminate entire sections, unless authorized by a supervisor or indicated in the template.

6.6.3. If the firm is a warehouse only, use the FICS-Warehouse template. However, if the firm is subject to 21 CFR 123 (Seafood HACCP) you must use the main FICS template.

6.6.4. When writing violations in the Summary Section and Discussion with Management Section, do not write in the form of an order (as done in the State inspection report). These must be turned into statements using language that describes violations in the context of the processes observed during the inspection.

6.6.5. Complete the following header information on page 2:

a. Firm Legal Name

b. Firm FEI Number

c. Inspection Dates

6.7. Complete the FICS: Firm Data Table

6.7.1. Complete all applicable sections of the Firm Data table using the guidance below.

6.7.2. Firm Legal Name and DBA Name

a. This is the firm name that the firm is incorporated with and uses on the articles of incorporation (if applicable)

b. This may not be the same name as listed in LIS.

c. Do not include Doing Business As (DBA) names in this section.

6.7.3. The location address is the current address the firm is producing/storing product. If the address is different than noted on the assignment eSAF coversheet, make a note/explanation in the Summary section of the report (see 6.9.7.f)

6.7.4. The mailing address recorded is the mailing address of the firm/location inspected, not of a corporate headquarters. However, make a note of the corporate address. If the firm does not receive mail at the firm's address, write an explanation in the summary section.

6.7.5. Record an email address for every firm when one is available. Use a generic email if the firm has one. Otherwise, use the contact email address supplied by the firm. Do not use a website for this section.

6.7.6. Type the name of the inspector that was assigned to the inspection. This may or may not be the lead inspector.

a. Some team inspection assignments may have a lead inspector who is different from the inspector assigned; for example on environmental sampling assignments. Complete the lead inspector section only if it is different than the inspector assigned.

6.7.7. List all additional inspectors that participated in the inspection even if they were not there for the entire inspection.

6.7.8. Indicate the number of FDA Contract Samples collected and the analysis. Further details regarding the samples should be captured in the summary section.

6.7.9. Mark the applicable inspection types.

6.8. Complete the FICS: Inspection Data and State Compliance Follow Up tables

6.8.1. The PAC Code identifies the type of inspection. The following PAC Codes should be used:

a. 03S001 - GMP Component – all inspections should use at least this code

b. 03S002 – Fish/Seafood HACCP

c. 03S005 – Low Acid Canned Food or Acidified Food

6.8.2. Complete the Establishment Code based on the descriptions below

Code	Establishment Type	Description
Y	Labeler/Relabeler	An establishment which affixes the original labeling to a product or changes in any way the labeling on a product without affecting the

		product or its container.
M	Manufacturer	Makes a new or a changed product from one or more ingredients.
MA	Manufacturer, Acidified	Firm which manufactures/produces acidified food products as outlined in 21 CFR 114.
ML	Manufacturer, Low Acid	Firm which manufactures/produces low acid canned products as outlined in 21 CFR 113.
R	Re-packer/Packer	The establishment packs a product or products into different containers without making any change in the form of the product. Includes packers of raw agricultural products.
X	Salvage Operation	The retailers, wholesalers, re-packers, and underwriters who deal primarily in the resale and reconditioning of damaged goods.
WA	Warehouse- Ambient Storage	A facility that holds/stores consumer products at ambient air temperatures only. Ex: warehouse,
WZ	Warehouse – Ambient, Refrigerated, Frozen Storage	A facility that has three separate areas (or any combination) within the facility to hold/store any food based on the required temperature range of the product being held (ambient, refrigerated or frozen storage). Example – the facility can hold frozen raw fish; pasteurized crabmeat; and canned fish at the appropriate temperatures all at one facility.
WF	Warehouse – Frozen Storage	A facility that holds/stores food at frozen temperatures (approximately 32°F or below) only. Examples are facilities storing frozen raw seafood; frozen fruits or vegetables products, etc.
WR	Warehouse – Refrigerated	A facility that holds/stores food at refrigerated temperatures (approximately 45°F –32° F) only. Examples are vegetables, fruits; raw seafood; or food where refrigeration is used as a barrier to additional microbial growth.

6.8.3. Complete the Product Code and Product Description portion for products covered during the inspection.

a. Use the *FDA Product Code Builder (PCB)* to identify the proper 7-digit product code for the highest risk product(s) covered during the inspection. Refer to the online *Product Code Builder Instructions* for more information on how to use the PCB.

b. Copy the description from the PCB and paste into the product description box on the form.

c. Multiple Product Codes can be entered for any of the PAC Codes.

Warehouse Specific Instructions:

d. If the facility is a warehouse only and holds products that fall under many industry codes, enter 47 as the product code. The 47 product code should be used just for warehouses that have many different products, e.g. grocery or restaurant suppliers.

e. If the facility is a Warehouse and holds products with just a few types of industry codes, list the specific product codes (up to 4) and denote the product descriptions for a few items. It is not necessary to enter product codes for every different item. Do not use 47 as the product code.

For example:

A snack food distributor that handles potato chips, pretzels, salsa, and bean dip would have industry codes for 07 Snack Food Items, 27 Dressings and Condiments, and 37 Mult Food Dinner/Grav/Sauce/Special.

6.8.4. Do not fill in any information under Supervisor Recommended Classification.

6.8.5. Hours

a. Complete the hours box for each PAC Code

b. Divide hours as appropriate based on the time conducted for each part of the inspection.

c. Include total hours for all inspectors that participated in the inspection.

d. Record hours as full or half hours.

e. Include all hours used to prepare for the inspection such as file review, research and the time used to complete all reports.

f. Do not include any travel time in the hours.

6.8.6. State Compliance Follow Up

a. Select the appropriate inspector recommendation (supervisor will modify in the case where there is a disagreement).

b. Refer to the *FOOD.30.02 - Reinspection SOP*.

6.9. Complete the FICS: Summary Section

6.9.1. Limit character use to 3500 characters total including spaces. Use review tab/word count to verify that the limit is not exceeded.

6.9.2. Do not use bullets or numbering in the Summary Section. eSAF does not transfer these characters appropriately.

6.9.3. Use complete sentences and paragraphs along with the template language provided where applicable.

6.9.4. Write information about the inspection type, date, and auditors (as applicable).

6.9.5. Description of the products must be descriptive enough to understand the types of product the firm handles, distributes, manufactures, etc.

a. Identify the products (general descriptions of categories of foods produced or warehoused could be taken from industry codes), state (ambient, frozen, and refrigerated) of the products, whether its consumer ready packaging, and any other production information pertinent to assess the risk of the product (such as Ready to Eat, ROP packaging, LACF or AF processes. Also include other non-food products that are under the jurisdiction of FDA including animal feed, pet food, dietary supplements, drugs (prescription or non-prescription), medical devices, or cosmetics. See *Appendix A – Definitions – Other FDA Products* located at the end of the SOP.

Examples:

- This firm manufactures coffee. They also warehouse and wholesale teas, bottled water and various soft drinks.
- This firm is a Low Acid Canned Food processor of seasonal vegetables including corn and peas
- This firm is a bakery manufacturing bread, buns, and sweet rolls which are sold as ambient products in consumer ready packaging. They also manufacture a granola mix.
- This firm is a processor of fish including tilapia, salmon, and tuna which are sold refrigerated in bulk lot cases, and ready to eat seafood salad which is sold refrigerated in consumer ready packaging.
- This firm is an ambient temperature warehouse of snack foods including chips, dips and salsa in consumer ready packaging.
- This firm is an ambient temperature warehouse only, storing food, pet food, and paper goods.
- This firm is a dried tea manufacturer and also manufactures non-prescription drugs.

b. If a firm is a manufacturer, it is not necessary to add any warehousing activities when they simply support the manufacturing operation. DO add warehousing activities if they are for products that are not part of the manufacturing operation.

Example: The firm is a manufacturer of pizza dough sold as a frozen product, a refrigerated warehouse of prepared produce, and frozen warehouse for meat pizza toppings.

6.9.6. Utilizing the information from eSAF, summarize the previous inspection results. If deficiencies were noted in the previous inspection, document any corrections made to address those deficiencies that were visually verified (as appropriate) during the current inspection. This part must be very concise; if there were a lot of violations or corrective actions taken, this detail must be written in Inspection Results Section, however a statement indicating this must still be included in the summary section.

6.9.7. Summarize notable observations from the current inspection.

a. Include the highest risk product in production/handling covered during the inspection. This information is also noted in more detail later in the FICS.

b. Note the types of violations such as protection from contamination, food contact surface sanitation, equipment clean-ability, etc. This section must be very concise and is a summary.

c. Document any administrative action that is taken with the firm - such as sanitary notice or embargo. Example: A Sanitary Notice was issued due to a rodent infestation; live and dead rodents found and food ingredients were contaminated due to chewing, and presence of droppings.

d. When significant violations are identified such as a lack of a HACCP plan or CCPs identified, write a statement regarding the process controls that were observed to address the safety of the products produced. Example: The issue is administrative because the CCP monitoring is actually in place.

e. Document all corrective action taken by the firm to address violations from the current inspection. All corrections must be directly verified by the inspector(s).

f. If the firm's current address is different than what is noted on the eSAF cover sheet, write an explanation of the change. For example: The firm has moved to a new location; they are no longer operating at the 123 Main St, Anytown MN location.

g. If the firm legal name has changed or is different than what is on the eSAF coversheet, provide an explanation. Example: This firm previously operated as Frito Lay, Inc. and now operates as Rolling Frito Lay Sales LP; this is a change in the corporate structure only.

h. Summarize any FDA assigned complaints that were investigated.

i. Summarize any samples collected and the results of the analysis. If the analysis has not been completed at the time the FICS is to be submitted to the supervisor, leave the results section blank.

6.9.8. Document the firms FDA Registration status.

6.9.9. Refusals – Document that no refusals were encountered. Refusal to sign a state inspection report is not considered a Refusal of Inspection. If other inspection refusals are encountered (access to records, taking of photographs, access to parts of the facility, etc.), follow procedures in *FOOD.30.01 - Inspection Protocol – Food Manufacturing SOP*.

6.10. Complete the FICS: Inspection Results -FDA Jurisdiction and Interstate Commerce

6.10.1. Collect and enter percentage information about the following:

a. Incoming ingredients or products from out-of-state suppliers or international shippers. If the firm does not purchase directly from out of state or international suppliers, but products are labeled as manufactured or distributed by an out of state firm, document that activity.

b. Products sold to out-of-state or international customers.

c. Products that are sold wholesale (not sold to the ultimate customer). If products are only shipped to another location owned by the same company – consider this wholesale sales.

d. Products sold via the Internet. Products sold via the Internet and shipped by common carrier are considered to be interstate commerce.

6.10.2. Determine the firm's biggest selling items (based on units/volume not dollars in sales) and who are their major customers and document the firm's general promotion and distribution patterns.

Examples:

- This firm distributes bakery products such as bread, buns, and cookies to retail grocery stores in Minnesota, Iowa, and Wisconsin.
- This firm primarily distributes dried honey to a food manufacturer in DeKalb, IL

6.10.3. Document the product, physical address, and name of supplier or customer on the FICS used to establish FDA jurisdiction.

a. For food manufactures, list one raw material or ingredient received from out of state or one product shipped out of state.

b. For a warehouse or distributor, list one FDA regulated product (e.g. NOT a USDA shielded product) received from out of state or one product shipped out of state.

c. When a firms' internet sales represent the firms interstate commerce, include the firms' website

d. Collect a copy of documents used to establish FDA jurisdiction for violative inspections and attach as an Exhibit. Refer to Section 6.24 for further information.

6.10.4. If the firm has no direct sales outside of Minnesota or records of incoming ingredients from another state (interstate), but uses ingredients that originally came from another state, indicate that in that paragraph. Example: All ingredients are purchased from a local supplier within the state of Minnesota. Southern BBQ Sauce, one of the main ingredients, is produced by the I Love Sauce Corporation in Memphis, Tennessee.

6.10.5. When there is an apparent violative product noted during the inspection, establish and document examples of interstate shipments of the violative product(s); or if there are no such shipments, provide examples of interstate shipments of major components of apparent violative products. In either case, collect complete interstate documentation such as bills of lading, invoices, or other written documentation and submit as an Exhibit.

6.11. Complete the FICS: Inspection Results -Administrative Data

6.11.1. Indicate when the firm operates using the following descriptions:

a. Year Round – with a fairly regular schedule

b. Seasonally – specific months in the year (list specific months)

c. Periodically – occasionally, once a month, as needed based on inventory (list)

6.11.2. Document the approximate number of employees for the specific location at the time of the inspection. If the firm has seasonal employees, count those employees in the total number. Do not state a range – enter a specific number only.

6.11.3. Determine the Gross Annual Food Sales. The sales should only include FOOD.

a. MDA license fees paid can be a helpful indicator.

b. If the firm technically has no 'sales', use the value of product that moves through the facility.

c. If the MRP does not know and the firm is licensed by FFSD, contact licensing staff to request the GAFS category.

6.11.4. Only use the following categories for Gross Annual Food Sales on the FICS (these categories are different from MDA licensing categories):

a. $0 – 24,999
b. $25,000 – 49,999
c. $50,000 – 99,999
d. $100,000 – 499,999
e. $500,000 – 999,999
f. $1,000,000 – 4,999,999
g. $5,000,000 – 9,999,999
h. $10,000,000 – 24,999,999
i. $25,000,000 – 49,999,999
j. $50,000,000 and over

6.11.5. Determine and document if the firm has any alias names that they may operate under. This may include names Doing Business As (DBA) names or names the firm may have previously operated under

6.12. Complete the FICS: Inspection Results - FDA Resources

6.12.1. Record the resources that were handed out to the firm. These documents are to be provided and reviewed with the most responsible person at the firm during the opening meeting. Refer to the current FICS for the current year's requirements for information and documents to be provided to firms. Only document that these items were provided or discussed if in fact that occurred. DO NOT record any specific information about your discussion with the firm regarding these resources on the state inspection report.

6.13. Complete the FICS: Inspection Results - Persons Interviewed and Individual Responsibility

6.13.1. Identify the Most Responsible Person (MRP) at this location. Ask the individual claiming to be the MRP, whom they directly report too. If the person directly reports to someone at the location being inspected, the manager of this individual should be listed as the MRP. This process should be continued until the most responsible person is truly identified. Obtain and document the persons full legal name.

Note: The MRP is not the person who the firm would like contacted in the future. This is not the warehouse manager (if there is someone higher at the firm) just because he is the one who "deals" with the government.

6.14. FICS: Inspection Results - Firm Information and History

6.14.1. Determine the ownership of the firm. This needs to be an active inquiry to the MRP, not just based on the firm's license.

a. If the firm is a corporation, determine and list the state where the incorporation occurred (not necessarily the state where the firm is located) and the year in which it was incorporated.

6.14.2. List the principle officers of the corporation by name and their title. Common titles include: President, CEO, Vice President, Secretary, Treasurer, CFO, COO. Use titles appropriate to that corporation.

6.14.3. In the Chain of Command section, list the top management officials at that location and state their general areas of responsibility to establish who has the duty and power to prevent and correct violations. Include names and responsibilities of the persons that provided relevant information during the inspection. Always include who has authority to initiate capital improvements.

6.14.4. If the MRP at this location reports to someone at another location, include that person, their title, and where they are located.

6.14.5. Briefly describe the size of the firms operations. Note major changes to the facility since the previous FDA or MDA/FDA inspection.

6.15. Complete the FICS: **Inspection Results - Previous Inspection Results and Corrective Actions**

6.15.1. In instances when documentation of the last FDA or MDA/FDA Contract Inspection results and corrective actions exceeds the 3500 character limit, add significant text to this section. Include the detailed description of the previous inspection results and corrective actions in this section instead of in the Summary section. See section 6.9.6.

6.15.2. Delete this section if the previous inspection results and corrective actions are listed in full in the Summary Section.

6.16. Complete the FICS: Inspection Results - Complaint Review

6.16.1. Determine whether the firm maintains complaint information. This should include consumer complaints or those from another manufacturer.

6.16.2. If the firm maintains written records, review the complaint files since the last inspection or at least one year prior to the current inspection date. If there is no actual hardcopy file to review, then having the discussion with the firm's management would be sufficient.

6.16.3. Evaluate complaints as follows:

a. are there common types of complaints received by the firm;

b. are there trends that may indicate processing failures, sanitation or employee practices deficiencies;

c. firms that have more specialized processes (such as LACF) the requirements are very different and complaints should be looked at more closely;

d. determine the firms system for tracking, trending, reviewing, investigating, and corrective actions.

6.16.4. From the review, determine what complaints warrant any follow up or further investigation. For example, if there is one or multiple complaints of metal shavings found in a product, looking into the production line used to manufacture that product would be

warranted. A complaint regarding insects in a finished product may warrant a more detailed review of pest control records. However a complainant saying their cake did not raise properly is more of a quality concern and not an issue that warrants inspection follow up.

a. Ask what investigation the firm had conducted since being notified of the complaint and what root causes had been found.

b. Try to determine the root cause of the problem, especially if the firm failed to take action on their own.

c. Determine what did the firm did with the product that may have remained in distribution (recall, nothing, etc.).

6.16.5. Document the time range of records reviewed (Example: April 2012 through March 2013) and the outcome of the review including the complaint dates, product(s) involved, the nature of the complaint and the firm's resolution.

6.16.6. If the firm refuses to provide this complaint information follow procedures in FOOD.30.01 Inspection Protocol – Food Manufacturing

6.16.7. Evaluate any assigned FDA complaints that are attached in the Document Set. Document if the firm was aware of the complaint and any actions the firm took to address the complaint. Delete this paragraph if there are no FDA assigned complaints

6.17. Complete the FICS: Inspection Results - Recalls and Maintenance of Records

6.17.1. Identify if the firm has a recall plan in place.

6.17.2. Determine and document whether the firm has been involved in a recall since the previous inspection. This can be done by questioning the firm. If yes, list the recall dates, affected product(s), and any problems that may have occurred with locating or retrieving the product.

6.17.3. List the date and results of the last mock recall conducted by the firm. If the firm does not conduct mock recalls, state this information in the FICS.

6.17.4. Determine if the firm has established records identifying the immediate previous supplier of all foods, food ingredients and packaging materials (if a manufacturer) along with the subsequent recipient of all foods, food ingredients and packaging materials (if a manufacturer) as required by the Bioterrorism Act (BT Act).

a. Research if the firm maintains the required records for the appropriate minimum time period as required by the BT Act.

b. Record maintenance required by the BT Act is as follows:

i. All domestic persons in the U.S. that manufacture, process, pack, transport, distribute, receive, hold or import food; foreign persons that transport food; and persons who place food directly in contact with its finished container are required to maintain records.

ii. For these regulations, the term persons include individuals, partnerships, corporations, and associations.

Type of Food	Record Retention for Non-	Record Retention for

	Transporters	Transporters or Persons Keeping Records on Their Behalf
Food having significant risk of spoilage, loss of value, or loss of palatability within 60 days	6 months	6 months
Food having significant risk of spoilage, loss of value, or loss of palatability occurring after a minimum of 60 days but within 6 months	1 year	1 year
Food having significant risk of spoilage, loss of value, or loss of palatability occurring no sooner than 6 months	2 years	1 year

c. Refer to the FDA Document: *Establishment and Maintenance of Records* for a list of required record information for non-transporters and transporters of food.

6.18. Complete the FICS: Inspection Results - Products and Processes

6.18.1. Write a detailed account of the firm's handling of the product(s) that are the focus of the inspection (the highest risk product being produced or handled during the inspection). This is to be written in a narrative format.

6.18.2. If they also produce higher risk products that were not covered during the current inspection, document the products with a brief description and note that they were not being produced or handled during the inspection.

6.18.3. Include the following information in the detailed description of the highest risk product being produced or handled during the inspection:

a. Raw materials used and how they are received.

b. Major processing steps

c. Types of equipment used in critical processing steps.

d. Firm's established critical limits or other controls.

e. Packaging process and materials.

f. Identify if the process is automated or manual

g. Verified measurements of processing critical limits, storage temperatures, etc.

h. Flow Diagrams – A flow diagram is not required but may be included as an attached Exhibit to supplement the detailed written description.

i. Schematics, photographs, or formulations may be included as Exhibits to clarify a process or equipment as needed. This may be especially applicable if violative product is found.

6.18.4. For specialized processes, greater detail is needed for the product and process description. The detail must support the evaluation of the product and processes that is required in the HACCP section of the FICS and other supporting documentation.

6.18.5. List names and sources of new or unusual components, raw materials, or equipment. Specifically, report changes to the firm's general overall operations, including significant changes in equipment, processes, or products since the previous inspection.

6.18.6. List types of production records reviewed relevant to the products being produced. Example text may include the following: mock recall conducted on 10/9/2015, backflow documentation from most recent servicing done on 6/23/2015, scale calibrations from 3/9/2015, production records including critical factor documentation from 8/27, 10/20, and 11/28/2014 and 1/19, 6/6, and 9/17/2015, filed processes and supplemental filed processes associated with production records reviewed, deviation log from 2015 production, boiler treatment chemical documentation, and calibration logs for equipment monitoring critical factors.

6.19. Complete the FICS: Inspection Results - Seafood HACCP Plan Review

6.19.1. Complete this section when 21 CFR 123 Fish/Seafood HACCP regulations apply at the firm. This section does not need to be completed for GMP only, Acidified Food and Low Acid Canned Food and can be deleted from the final document.

6.19.2. Identify and document all products for which the firm has conducted a hazard analysis including the process, packaging, and other details about the product as appropriate.

6.19.3. Identify the specific product(s) reviewed including processes used to produce it. Include justification for why the specific products were chosen for review such as highest risk, plan not reviewed previously, etc.

6.19.4. Identify and document the HACCP trained individuals and their responsibilities at the firm (specific to the Seafood HACCP), i.e. who conducted the Hazard Analysis (HA), wrote the HACCP Plans, conducts record review, etc. If the hazard analysis was conducted by an outside entity/individual, document accordingly.

6.19.5. Document that an inspector conducted hazard analysis was completed, If hazards are present, identify and what hazards need to be controlled including what step they occur at based on the detailed process description noted in the Products and Processes section.

6.19.6. Submit the Inspector Conducted Hazard Analysis form(s) as an Attachment for every inspection.

6.19.7. If a HACCP Plan is required to control hazards, complete the following:

a. Obtain a copy of the firm's HACCP plans for all plans reviewed (complete reviews and technical review) during the inspection and include as an Exhibit. Ensure the page with the firms' date/signature (documenting the annual review) is collected and submitted.

b. Document any differences in the hazard identification noting the specific step and specific hazard that you determine should be a CCP. Additionally, note any process controls the firm may have in place for the hazards not specifically identified in the HACCP plan that could ensure the product is safe. If there are no differences, document accordingly.

c. Document the firm's identified CCPs and the hazards they are controlling. Note if the procedures identified are adequate to control the hazards.

d. Observe the firm personnel conducting the monitoring steps for the CCPs noted in the HACCP plan (those that are necessary for safety of food products). Document the monitoring activities observed and any discrepancies and note why they do not match the HACCP plan.

e. Document HACCP plan records reviewed. Document in detail any deficiencies noted from the records review. Collect violative records, reference in the report and mark as Exhibits. Document applicable sanitation records reviewed based on the firm's process and handling. Document any deficiencies in detail. Complete this step even if a HACCP Plan is not required. Collect violative records, reference in the report and mark as Exhibits.

6.19.8. Complete form 3501 for all plans reviewed during the inspection (complete reviews and technical review) to reflect findings. If a HACCP Plan is not required, only complete the sanitation information in the form. Submit all completed 3501forms as Attachments.

6.20. Complete the FICS: Inspection Results – Fish/Seafood Species Fraud Evaluation

6.20.1. For inspections assigned as Seafood HACCP, evaluate fish and seafood products for seafood fraud.

a. Select species/products for review based on examples of substituted seafood at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm071528.htm

b. Review incoming invoices, product and package labeling, and outgoing invoices for consistency and any discrepancies noted that may require further follow up.

6.20.2. Document the products/species that the firm handled and that were reviewed and the findings on the FICS and collect evidence as appropriate to support the observation.

6.20.3. Follow procedures in *FOOD.30.27 - Field Compliance Actions SOP* for products confirmed or suspected to be in violation and are or may be misbranded. Samples may need to be collected to verify the findings from record review. Contact a supervisor for further instructions.

6.21. Complete the FICS: Inspection Results - QA System Evaluation

6.21.1. Evaluate the quality assurance systems in place in the facility. Apply requirements based on the firms' operations (i.e. processing/manufacturing vs warehousing only).

6.21.2. Review the firm's training program. In particular, look for training covering the following: GMP requirements, handwashing procedures, sanitation procedures, use of footwear and footbaths/foamers, outer-garments, gloves, hair restraints, etc. In particular, list training topics that are unique, or unique methods of delivery (multi-lingual). Document as noted on the FICS how the inspection observations compare to the described training program. Example: During inspection, employees were observed wearing hairnets and beard nets, clean uniforms and glove use.

6.21.3. Review the firm's policies/procedures related to food employees displaying symptoms of or diagnosed with foodborne illness or open lesions and how employees are trained. Document as noted on the FICS.

6.21.4. Review the firm's policies and procedures related to cleaning and sanitizing of the facility and equipment. In particular, cover the following:

a. Frequency and time period that sanitation operations are conducted.

b. Whether the firm conducts dry cleaning processes or wet cleaning processes and the types of detergents and sanitizers that are used.

c. How sanitizer concentrations are verified.

d. Environmental monitoring program, including frequency of testing, collection locations or how those are determined, target organisms and their corrective action plan. Review environmental monitoring records for a designated period of time, evaluate the results, and document significant findings including corrective actions taken by the firm.

e. Finished product testing program, including products, frequency, collection locations, target organisms and if corrective action plan exists.

f. Review sanitation records for a designated period of time and evaluate the results. Document records reviewed including dates, for example: Cleaning and sanitizing documentation including allergen cleaning verification January 1/2/2014 – 11/23/15, environmental monitoring standard operating procedure (SOP) and environmental swab laboratory results 7/2/14 – 11/23/15, and pest control logs 12/30/15 – 11/23/15.When violations are noted regarding sanitation issues, detail should be provided about records the firm maintains relative to the violation. For example: if rodent evidence is prevalent throughout the facility, specific comments related to pest control practices and records should be included.

6.21.5. Assess requirements for incoming ingredients, products and packaging materials such as a Certificate of Analysis, Letters of Guarantee, etc. and with what frequency the documents are required.

6.21.6. Review receiving procedures and incoming products including temperature monitoring for temperature sensitive ingredients, ingredient testing especially for microbiologically sensitive ingredients such as sliced deli meats, refrigerated RTE ingredients, etc.

6.21.7. Document the major food allergens used/present in the facility and the primary controls which may include sanitation practices/verification, production scheduling, protective clothing for employees, finished product labeling, etc.

6.22. Complete the FICS: Inspection Results - Label Review

6.22.1. This section must be completed at firms that manufacture or label/re-label food products. This section should be deleted from the FICS if the firm only handles pre-packaged food items.

6.22.2. Evaluate labels of food that is manufactured, labeled or re-labeled at the firm for accuracy. Refer to *FOOD.30.01 Inspection Protocol – Food Manufacturing SOP*.

6.22.3. Review three different product labels during each inspection for basic food labeling, FALCPA, and NLEA requirements. If NLEA is not applicable because all products from the firm are exempt, document this information including the reason the products are exempt (e.g. which exemption is applicable) see21 CFR 101.9(j)(18)(iv). Document the products reviewed on the FICS.

6.22.4. Issue orders for all labeling violations on the State Inspection Report and document observation on the FICS.

a. Describe in the FICS specifics of the label deficiency vs what was observed, e.g. ingredients you saw going into the product and why/what the deficiencies were.

b. For violative products, you should collect a Bill of Lading for the finished product to document interstate commerce, and if applicable, a bill of lading for a raw material would be good as well.

6.22.5. Collect four physical/original labels for each under the following violative or suspect conditions:

a. Label does not identify the presence of a major food allergen.

b. Label does not identify functional ingredients (e.g. color additives, such as FD&C Yellow 5; chemical preservatives such as sulfiting agents [sulfur dioxide, sodium sulfite, sodium bisulfate, potassium bisulfate, sodium metabisulfite, and potassium metabisulfite]

c. Label does not bear nutritional labeling and the firm is not exempt

d. Label contains unauthorized health claims or nutrient claims

e. Label does not identify significant nutrition or other mandatory labeling requirements, e.g., absence of trans fat; serving size

f. Products subject to regulation as conventional foods but are labeled as dietary supplements or medical foods

g. Labeled as juice that do not bear percent juice labeling

h. Ensure that every label that would go on the package is collected, e.g. not just a front or back part

6.22.6. If a finished product label is collected for missing major food allergens or lacking ingredient declarations, raw material/ingredient labels must also be collected (or photographed when the label cannot be removed) as evidence that a finished product is in violation. Only one label must be submitted.

6.22.7. Collected labels must contain firm's product coding unless it is not possible. A "dummy" label can be included if no other option is available but product coding description must be included.

6.22.8. Under very limited circumstances, photographs of labels can be taken in lieu of physical label collection. These circumstance may include labels of a size too large for practical submission, labels that cannot be separated from the packaging, etc. Again, ensure that all parts of the products label are photographed, e.g. not just a front or back part, and that the photographs are fully legible.

6.22.9. Mount or tape each label on a separate 8.5x11 in piece of paper and label each piece of paper with the firm name and date of the inspection unless it is not possible or would obscure such as a cereal box or round container.

6.22.10. Submit three original product labels marked as Exhibits to the reviewing supervisor or Contract QAC (these will be submitted to FDA) and the fourth label submitted to MDA per *FOOD.30.24 – Label Review Sampling SOP*. Document on the submission record that the labels were collected during an FDA Contract Inspection.

6.22.11. If there are no label violations, indicate that in this section.

6.22.12. If there is a request for FDA review of the label, indicated this in the Summary section.

6.23. Complete the FICS: Inspection Results - Discussion with Management

6.23.1. Document the names and titles of all firm personnel that attended the exit interview.

6.23.2. List the significant objectionable conditions observed based on the GMPs. This section should include observations, locations, and why the objectionable conditions noted are important i.e. the impact on food or food production processes.

For example,

- The required HACCP plan did not identify all food safety hazards that are reasonably likely to occur - specifically, the plan for vacuum packaged imitation king crab meat does not identify *Clostridium botulinum* growth and toxin formation as a hazard reasonably likely to occur at the receiving, storage and staging steps 21 CFR 123.6(c)(1)
- Inadequate methods are used for cleaning and sanitizing equipment and utensils – specifically several kitchen employees were noted dipping various utensils in the sanitizer compartment and removing immediately without meeting the 60 second contact time required for the quaternary sanitizer on 7/10/12. 21 CFR 110.35(d)(5).

6.23.3. State the response from the firm's management related to objectionable conditions such as planned resolution and/or completion in specific timeframes/compliance dates. This should be an active inquiry regarding the firms' intent to comply. If the MRP is not able to make a commitment to a compliance date, indicate that on the report. For example: Mr. Jones stated they intended to comply, but could not provide a specific compliance date. Do not write as a 'Comply by' date – write as a statement. For example: 'Mr. Jones stated the floor would be resurfaced by the compliance date of 11/4/13'.

6.23.4. List any corrections that were made during current inspection. These corrections should be visually verified and the corrections documented (not just stated as corrected).

6.23.5. Describe any samples collected as part of the inspection, the purpose, the analysis requested, etc. Reference Sample Collection Maps, Sample Records, photographs of sample sites, and final sample results in the description and attach these documents as Exhibits.

6.24. Complete the FICS: Inspection Results - Exhibits &Attachments

6.24.1. List the additional documents that are submitted as Exhibits or Attachments. These are to be uploaded to the SP document set or submitted as hard copies (such as labels).

6.24.2. Any documents collected at the firm as documentation of compliance or evidence of violations must be documented as Exhibits. Any documents generated by MDA in support of the inspection must be documented as Attachments.

a. Examples of Exhibits include (but are not limited to) labels, records, HACCP plans, firms' lab results, firm's SOPs, bills of lading, or photographs.

b. Examples of Attachments include (but are not limited to), sample collection records, laboratory sample results, spreadsheet summarizing the firms

environmental sampling results or violations, Form 3501 or 3511, or inspector conducted hazard analysis

c. The documents are to be referenced in the State Inspection Report (with the orders, observations or in comments) and in the FICS. Number them sequentially as they are referenced in the State Inspection Report. For example: Exhibit 1, Attachment 1, etc.

d. Mark the individual documents on each page to include, the Exhibit/Attachment number, the name of the firm, FEI number, inspection date, collector's initials and page number (page x of y). This can be handwritten, a computer generated/printed label (appropriate when there are many documents or pages that are collected), or text inserted on a pdf document.

e. Mark the exhibits in the section at the end of the FICS, Include a brief description of the document. For example Exhibit #3 - Bill of Lading dated 10/30/13 for 'MN Best BBQ Sauce'

6.24.3. Type your name, job title, and date the FICS was submitted. If revisions are made at a later date, add the date the revised documents were submitted.

6.25. Preventive Controls Data Collection

6.25.1. Collect relevant data and complete the GMP/PC Data Form. The data is to be collected by interviewing the most responsible person at the firm at the time of the inspection.

6.26. Submit Report

6.26.1. Following the completion of the Inspection or Visit, upload to the SharePoint document set the state inspection report, FICS, and all attachments/exhibits within **four** business days.

6.26.2. Document incorrect or updated information on the eSAF coversheet including address, point of contact, and product codes that are no longer applicable or correct. Print the eSAF cover sheet, make corrections and scan and upload to the Document Set or make edits in Adobe.

6.26.3. Password protect documents created or collected solely as part of the FDA Contract inspection. This includes the FICS, Exhibits or other attachments, the eSAF coversheet, 3501, 3511 forms, etc. State Inspection reports do not require password protection. The current years' password will be provided during the annual contract training. Refer to the guidance document on instructions for password protecting Word or Adobe documents.

6.26.4. Use the following naming conventions when uploading the documents:

a. FICS – Word: Firm Name_City_Date_FICS

b. State Inspection report(s) (PDF): Firm Name_City_Date_Attachment 1 MDAInspectionReport

c. eSAF Cover Sheet (PDF): Firm Name_Attachment 2 eSAF Cover Sheet

d. PC Data Form: Firm Name_City_Date Attachment 3 PC Data Form

e. Specialized Processes Forms – PDF:

- Firm Name_City_Date Attachment x Seafood HACCP 3501-
- Firm Name_City_Date Attachment x LACF 3511
- Firm Name_City_Date Attachment x AF 3511-2

f. Required HACCP Plans – PDF:

- Firm Name_City_Date Exhibit x Seafood HACCP Plan- Tuna Salad-

g. Inspector conducted Hazard Analysis for each Seafood product evaluated: Firm Name – Attachment x Inspector HA

h. Other documents: Firm Name_City_Date_Exhibit x or Attachment x (appropriate name of document)

6.26.5. Documents that cannot be scanned and uploaded should be provided to the reviewing supervisor via mail or hand-delivered. This may include original labels, oversized flow charts, etc.

6.26.6. Refer to the *FDA Contract Inspector SharePoint Instructions* regarding the completion of inspection information and documentation in SharePoint.

6.26.7. Add or update metadata in the SharePoint Document Set as follows:

a. DBA (DO NOT change the Name* line – this will affect the Workflow)

b. Address, City, Zip, County if the location address changed since the assignment was made initially

c. USAFS Facility ID

d. Risk Level, Firm Type

e. Inspection Completion Date

f. Hours (total for all PAC codes)

6.26.8. If any documentation is returned for corrections, changes must be made and resubmitted within **two** days.

6.27. Conduct Reinspections, Follow-Up Inspections and/or Submit Firm Response

6.27.1. Conduct Reinspections or Follow-Up Inspections or Reinspections per *FOOD.30.02-Reinspection SOP*. Copies of these reports will be provided to FDA as documentation of compliance or non-compliance. Neither reinspections nor follow-up inspections (or other further compliance actions) are charged for under the FDA Contract.

6.27.2. Submit to your reviewing supervisor with three (3) days, any response that a firm provides to you (emails, letters, reports, etc.) as follow up to the Contract inspection. These responses will be provided to FDA by the supervisor.

7. RELATED DOCUMENTS (includes References, Attachments)

FDA Contract Inspection Links

FICS

FICS-Visit

FICS-Warehouse

FSMA User Information Sheet

3501 Seafood HACCP Form and Instructions

3511 LACF Form

3511-2 Acidified Food Form

Establishment and Maintenance of Records

FDA Contract Inspection SharePoint Instructions

FOOD.30.01 - Inspection Protocol – Food Manufacturing SOP

FOOD.30.02 - Conducting Reinspections and Follow-up Inspections SOP

FOOD.30.05 - Report Writing SOP

Inspector Conducted Hazard Analysis form

Instructions for Seafood HACCP 3501 Form

Password protecting and naming files for FDA Contracts

Product Code Builder Instructions

GMP/PC Data Form

USAFS Guidance

8. EQUIPMENT/MATERIALS NEEDED

Inspection Equipment

9. SAFETY

All MDA employees must follow the personal protective equipment requirements and field safety guidelines outlined in the initial and annual Food Inspector safety training. Never enter an area or perform any job task that you think will result in injury or illness. If you do identify any unsafe conditions – STOP the inspection immediately and consult with the facility management or your supervisor regarding a corrective action for the hazard(s). Lastly, stick to the specific focus of your position and as always – THINK SAFETY!

Food inspection staff must follow the Verbal and Physical Assault of State Agriculture Inspectors Policy. If the firm's operators have a history of hostile behavior, speak with your supervisor before conducting inspection.

Before performing an inspection, ask firm about any physical or chemical safety issues in the firm. If the inspector has concerns about in-facility safety, please contact supervisor.

10. CIRCULATION

This document is circulated to the following: Manufactured Food Program Inspection staff, Manufactured Food Program Inspection Supervisors, Manufactured Food Program Manager, Compliance Unit, Manufactured Food Program Support Staff, Food Standards Coordinator, Assistant Division Director, and Division Director.

11. APPROVAL/DOCUMENT HISTORY

Minnesota Department of Agriculture
Food and Feed Safety Division

Document FOOD.30.19	Page **27** of **30**
Version #: **3**	Effective Date: 11/28/2016
Title: **FDA Contract Inspections**	

Document History		
Version #	**Status (I, R)**	**Change History**
1	**I**	**Initial Policy Drafting.**
2	**R**	**Revisions to reflect new procedures for 2015 Contract year. All updates are captured on the document located in the Previous Versions folder on SharePoint.**
3	**R**	**Revisions to reflect new procedures and changes in the Statement of Work. Change from DFID to FFSD based on division structure change.**

Approved By:	**Date**
DocuSigned by: 51BD2563BF5444D...	11/28/2016
Approved By:	**Date**

I = Initial document; R = Revised document

Appendix A: Definitions – Other FDA Products

Animal feed:
An animal feed is a food product defined under the food definition, but is intended for the use of food for animals **other than man** and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

Drug (21 US Code section 321(g)):
The term "drug" means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of **man or other animals**. A drug, unlike a device, will achieve is affect through **chemical action or by being metabolized by the body**.

Device (21 US Code section 321(h)):
A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. A substance (**other than food**) intended to affect the structure or any function of the body.

Biologics:
These are medical products and are used to treat disease and medical conditions (like a drug) or prevent or diagnose a disease. Examples include: Vaccines, blood and blood products, blood test screens, and gene therapies.

Medical Device:
Is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and **which does not achieve its primary intended purposes through chemical action within or on the body** of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
- Examples range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits and certain electronic radiation emitting products with medical application and claims (e.g., ultrasound products, x-ray machines and medical lasers).

Drug:
A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. A substance (other than food) intended to affect the structure or any function of the body. A drug, unlike a device, will achieve is affect through chemical action or by being metabolized by the body.

Biologics:
These are medical products as well, and can be from a variety of natural sources. These are used to treat disease and medical conditions (like a drug) or prevent or diagnose a disease. Examples include:

- vaccines
- blood and blood products for transfusion and/or manufacturing into other products
- allergenic extracts, which are used for both diagnosis and treatment (for example, allergy shots)
- human cells and tissues used for transplantation (for example, tendons, ligaments and bone)
- gene therapies
- cellular therapies
- tests to screen potential blood donors for infectious agents such as HIV

Dietary Supplement:
A dietary supplement is a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet. A "dietary ingredient" may be one, or any combination, of the following substances:

- a vitamin
- a mineral
- an herb or other botanical
- an amino acid
- a dietary substance for use by people to supplement the diet by increasing the total dietary intake
- a concentrate, metabolite, constituent, or extract

Dietary supplements may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. Some dietary supplements can help ensure that you get an adequate dietary intake of essential nutrients; others may help you reduce your risk of disease.

Appendix B – Amenable and Non-Amenable Food Items

Non-amenable species – products under FDA Jurisdiction

- Non-specified red meats: bison, rabbits, game animals, zoo animals, Cervidae (deer, elk, moose) – EXCEPT when USDA Inspection is required under MN Statute
- Non-specified birds: wild turkeys, wild ducks, wild geese
- Products with 3% or less raw meat; 2% or less cooked meat; or less than 30% fat, tallow, or meat extract.
- Products with 2% or less cooked poultry meat; less than 10% cooked poultry skins, giblets, fat
- Closed face sandwiches –i.e between 2 slices of bread or on a bun
- Labels/labeling of shell eggs. Egg washing, sorting, packing.
- Freeze dried egg products, imitation egg products, egg substitutes, dietary foods, dried np-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut or other ethnic delicacies.
- Cheese or vegetable pizza
- Meat flavored spaghetti sauce with less than 3% red meat; meat flavored spaghetti sauce with mushroom and less than 2% meat; pork and beans; sliced egg sandwich (closed face); frozen fish dinner, rabbit stew; shrimp-flavored noodles; venison jerky; buffalo burgers; alligator nuggets; noodle soup chicken flavor.

Amenable species – products under USDA Jurisdiction

- Cattle, sheep, swine, goats, horses, mules or other equines, ratites and squab.
- Domestic chickens, turkeys, ducks, geese, and guineas.
- Products containing 2% or more cooked poultry; 10% or more cooked poultry skins, giblets, fat and poultry meat in combination.
- Products containing more than 3% raw meat; 2% cooked meat; or 30% or more fat, tallow or meat extract; includes tamales, convenience meals, egg rolls meat salads, sambusas
- Open face sandwiches – wraps, burritos
- Meat pizzas and meat sauces (3% red meat or more); spaghetti sauce with meatballs; open face roast beef sandwiches; hot dogs; corn dogs; beef/vegetable pot pies.
- Chicken sandwich – open face; chicken noodle soup
- Shell egg of domesticated chicken, turkey, duck, goose or guinea.
- Egg breaking and pasteurizing operations.
- Egg products including dried, frozen, or liquid eggs with or without added ingredients.
- Catfish