



What to Expect When You're Inspecting - Manufactured Food



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Food Safety and Lodging Program

Poll

How many years of Manufactured Foods Inspection experience do you have?

- a) Less than 1 year
- b) 1-2 years
- c) 3+ years
- d) None – Only retail inspections so far.



Agenda

- ❑ Foundational Approach
- ❑ Pre-Inspection Activities
- ❑ Inspection Process
- ❑ Close out/Exit interview

FOUNDATIONAL APPROACH

Poll

Describe your training

- a) Here is your code book, go protect public health!
- b) Shadowing another inspector
- c) Classroom style instruction in person/remote
- d) Both b & c
- e) Other



Foundational Approach - Statutes & Definitions

Who are we inspecting?

- Facilities engaged in *manufacturing, processing*, packing, or holding food for consumption in the United States.

“Manufacturing/Processing”

- Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.

– 21 CFR 117

Foundational Approach - Statutes & Definitions

Examples of manufacturing and processing activities include:

- baking
- boiling
- bottling
- canning
- cooking
- cooling
- cutting
- distilling
- drying/dehydrating
RACs to create a
distinct commodity
- evaporating
- eviscerating
- extracting juice
- formulating
- freezing
- grinding
- homogenizing
- irradiating
- labeling
- milling
- mixing
- packaging
- pasteurizing
- peeling
- rendering
- treating to
manipulate ripening
- trimming
- washing
- waxing

Foundational Approach - Statutes & Definitions

“Holding”

- The storage of food and activities performed incidental to storage of a food
- Activities performed as a practical necessity for the distribution of that food
- Does **not** include activities that transform a raw agricultural commodity into a processed food.

Foundational Approach - Statutes & Definitions

Examples of Holding Facilities include:

- Warehouses
- cold storage facilities
- storage silos
- grain elevators
- liquid storage tanks.



Foundational Approach - Statutes & Definitions

Purpose:

- To evaluate the food safety and compliance of production processes during a typical day.

Goals:

- Build rapport
- Accurately assess food safety conditions
- Educate while you regulate

Foundational Approach – Inspection Authority

What is the FD&C Act?

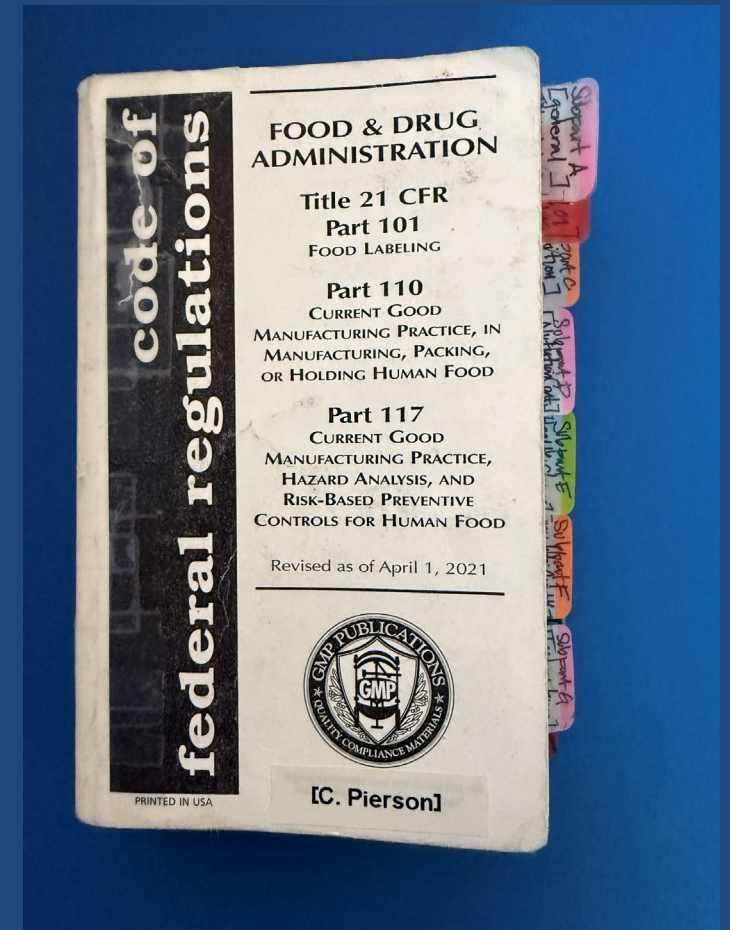
- It is a set of United States laws that authorizes the FDA to oversee and regulate the production, sale, and distribution of a wide array of public health products.
- The primary purpose of the FD&C Act is to promote public health by preventing fraudulent activity and protecting consumers from adulterated and misbranded products sold in the U.S.



Foundational Approach – Inspection Authority

The Code

- Title 21 of the Code of Regulation is the codification of the general and permanent rules pertaining to Food and Drugs
- The different parts of Title 21 CFR pertain to different types of inspections performed by FDA.



Foundational Approach - Inspection Authority

USDA:

- Meat from Livestock Animals*
- Poultry from Domesticated Birds*
- Egg Products

FDA:

- Non-meat Foods
- Seafood
- Wild Game
- Shell Eggs

State:

- Dairy (PMO)
- Cooperative agreements
- State-Authority

Foundational Approach – Inspection Types

cGMP Inspection

Foundation of all inspections: ensuring all requirements are met for:

- Personnel
- Plant & Grounds
- Sanitary Operations
- Equipment
- Warehouse/Distribution
- Defect Action Levels

Subparts A, B, F

Modified Inspections of Qualified Facilities

cGMP Inspection

Establish if the firm has attested:

Broad-based assessment of controls that are in place.

- Asking open ended questions
- Observing employees

Subparts A, B, D, F,

Foundational Approach – Inspection Types

Limited Scope PCHF

Broad-based assessment of controls that are in place.

- Asking open ended questions
- Observing employees

Subparts A, B, C, F, G

Full Scope PCHF

Comprehensive assessment of controls.

- Review of records
- Asking open ended questions
- Observing employees

Subparts A, B, C, F, G

Foundational Approach - Poll

What type of inspections are you tasked with?

- a) cGMP only
- b) Limited Scope-
Preventive Controls
Human Food
- c) Preventive Controls- Full
Scope
- d) Specialized Preventive
Controls
- e) None of the above



PRE-INSPECTION ACTIVITIES

Pre-Inspection – Research

We want to hear from you, please put your answers in chat!

***What kinds of information
do we need to collect during
Pre-Inspection Research?***

Pre-Inspection – Research



What do you look for?

- Name(s) of the Facility
- Processes taking place at the firm
- Standard of Identity for products produced at the firm
- Previous inspections and repeated violations

Pre-Inspection – Research

Where do you look for this information?

- Previous inspections and notes
- Firm's Website
- Social Media Platforms
- Previous FDA inspections
- Dun & Bradstreet



Pre-Inspection – Inspection Aids

Tools of the Manufactured Foods Inspector

- Calibrated Thermometer and wipes or other Sanitizer
- Inspection journal
- Flashlight
- UV light
- pH meter
- Sampling materials (Gloves, whirl-paks, swabs, scoops, etc.)
- Camera/phone
- Computer/tablet

What do I have on my person for any inspection?

- Work Phone (camera, email, and calling a supervisor)
- Calibrated Thermometers (1 handy and 1 backup)
- Sharpie
- Pens
- Flashlights (1 handy, 1 backup, 1 UV)
- Business Cards
- Alcohol Swabs for sanitizing thermometers
- Pocket Credentials (State & Federal)
- CFR Reference Book
- Sanitizer Test Strips
- Notebook



What do I have on my person for any inspection?

- Calibrated dual infrared / probe and lollipop thermometer with min/max temp
- Pens, sharpie and metal detectable pen
- UV light and Flash light
- Ruler for scale
- CFR 101, 110 and 117
- Sanitizer and pH test strips
- Alcohol swabs
- Hair nets
- State badge
- FDA pocket credentials
- Business cards
- Phone
- Notebook
- Prescription safety glasses



What else do I bring...

This bag comes with me inside the firm but not onto the production floor. It contains:

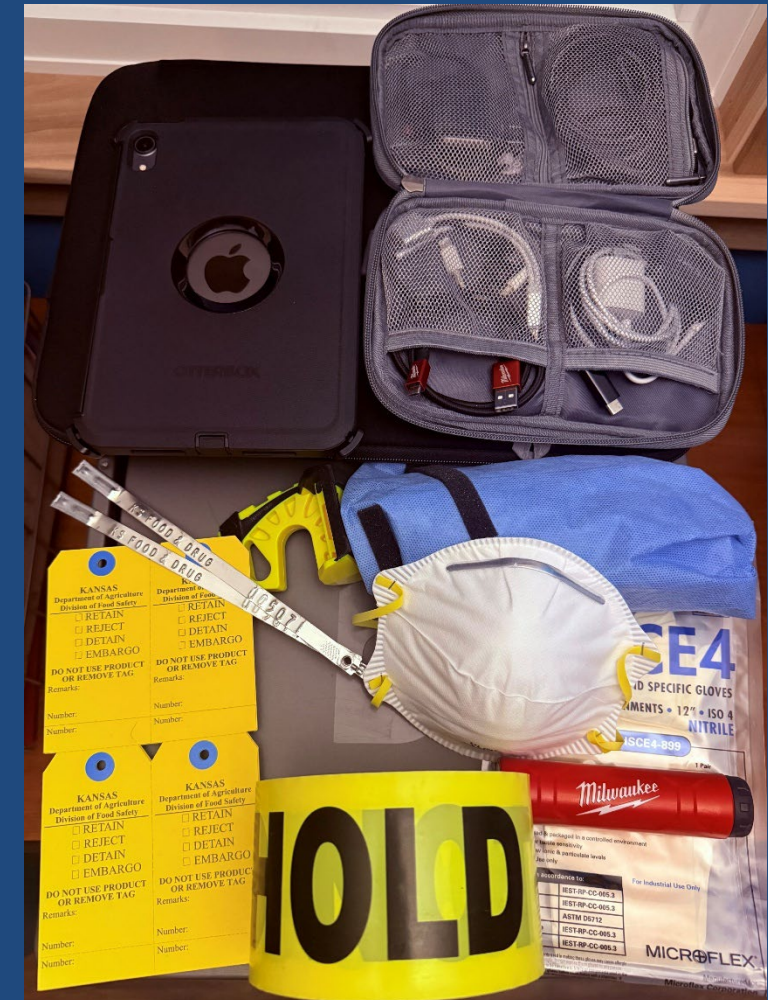
- inspection guides
- policy and procedure documents
- Sticky notes, paper clips, and removable flags for record review
- Inspection aids
- More back up pens and thermometers
- Locks – This bag is not always in my control



What else would I bring....



What else would I bring....



Vehicles may vary depending on Inspection types



Pre-Inspection – Inspection Notes - Poll



How are you keeping notes?

- a) Paper, Pen, Blank Notebook
- b) Paper, Pen, Checklist/prompts
- c) Electronic Notes
- d) Recording Devices
- e) Other

Pre-Inspection – Inspection Notes

How do you set your inspection notes up for success?

- Know what information you need to gather
- Use prompts with plenty of blank spaces
- Open ended prompts lead to open ended questions
- Attach your prompts to your notebook

Pre-Inspection – Inspection Notes

Building your
Inspection Prompts

Leave yourself plenty of
space to write

Know what information you
need

Don't be afraid to make
changes

NAME of FACILITY:		PHYSICAL Address:	Phone #
			Fax #
Date and Time of INSPECTION: Click or tap to enter a date.		MAILING Address:	Cell phone #
DAYS of Operation:		HOURS of Operation:	SOS registration #
Operational STATUS: <input type="checkbox"/> Year-round or <input type="checkbox"/> Seasonal		ENVIRONMENTAL monitoring program:	SOS valid/good standing: <input type="checkbox"/> YES or <input type="checkbox"/> NO
NAME of most responsible PLANT OFFICIAL:		TITLE of most responsible PLANT OFFICIAL:	Number of Employees
NAME of most responsible CORPORATE OFFICIAL		TITLE of most responsible CORPORATE OFFICIAL:	Inspection PAC codes
Annual GROSS SALES CATEGORY Code [0 thru 9]	Any RELATED firms [similar plants] in U.S: <input type="checkbox"/> YES or <input type="checkbox"/> NO	OUT of STATE % of sales [Finished product or incoming raw ingredients, establishing interstate commerce]:	
		% Received	% Shipped
	If YES [how many, city and state]:	% WHOLESALE [% of products sold business to business] % intra: % inter:	
	PARENT Company:	% RETAIL:	
		Previous PRODUCT and CODE # inspected:	
		Risk Category in USAFS:	
		Previous violations [COS/not CO	
		Websites/Social Media pages:	

Checklists and prompts

- ☐ **Coolers/Freezers (Subpart D)** [Temperature Control for Safety (TCS) foods for process, temperatures] and what products require TCS? Record temperatures on IR.
- ☐ **Training Program/Employee health/hygiene/records (Subpart A and F)** [restriction/exclusion, experience/education/training for assigned duties, training in food safety/hygiene, handwashing-when to wash, glove use and no BHC, record keeping requirements]. **Identify key personnel during the inspection and discuss.**
- ☐ **Handwashing sinks** [in processing area, easily accessible. Ready-to-eat (RTE) areas have accessible handwashing sink (no doors between)].
- ☐ **Food Safety Plan/HACCP (Subpart C)** [CCP's thermal, pasteurization, time/temperature, pH, aW, review records, does the firm have a written FSP, HA and/or written PC programs in place, PCQI]. Are controls in place and being implemented? Active managerial controls.
- ☐ **GMP's/SOP's/SSOP's (Subpart B)** [hairnets, beard nets, jewelry, etc.]. What does the policy address and is it being followed? Implemented?
- ☐ **Floors, walls, ceilings, lighting, doors/openings protected** [smooth, easily cleanable, lighting shatter shield/protected, drains].
- ☐ **Labels/Compliance** [all ingredients listed on label, cross referenced with product followed] recipe/formula, allergen declaration, sub-ingredients, nutrition, net weight.
- ☐ **Allergens** If the firm receives, stores and/or uses any allergenic ingredients, controls need to be in place for **allergen cross-contact** and/or **undeclared allergens** or both [milk, egg, fish (anchovies, cod, etc.) **crustacean shellfish**, **tree nuts** (almonds, pecans, walnuts) **peanuts**, **soybean**, **sesame** and **wheat**]. Is sequencing of product scheduled accordingly and what is process?
- ☐ **Equipment/Utensil** Constructed of suitable materials, **food grade**/food contact, **easily cleanable**, **designed**, properly **maintained**; **smooth**. Compressed gas/air.
- ☐ **Cleaning/Sanitizing (Subpart B)** procedures, equipment, utensils, parts, pieces. **Color coding policy/designation of equipment**. Types of cleaning/sanitizing methods (**wet/dry/foam**, **COP/CIP**), procedures in place, titration/test strips, concentration range per mfr. label, MSS, frequency, changeovers, dedicated crew or 3rd party.

Reminders:

Food Processing Inspections –

Do not sign anything (including visitors log) that inhibits inspectional authority, [rights removed for photography, etc.]. No photocopying or pictures of ID's/badges. Establish that firm is registered under the Bioterrorism Act and is aware of the Reportable Food Registry (RFR). Check ownership (SOS), facility size/sq. footage, risk category, hours/days of operation and any other relevant facility/operation information. Add additional facility sub-classifications in USAFS to help with database queries and environmental sampling selection. **Upon arrival to facility and prior to performing walk-through inspection, ask to review pest control, complaint logs, floor plan/process flow diagram, production schedule and copy of a label for product followed during inspection.** *Items highlighted below in grey should be obtained and referenced as necessary prior to inspection and as applicable to regulatory requirements.*

INSPECTION PROCESS

Inspection Process – First Steps

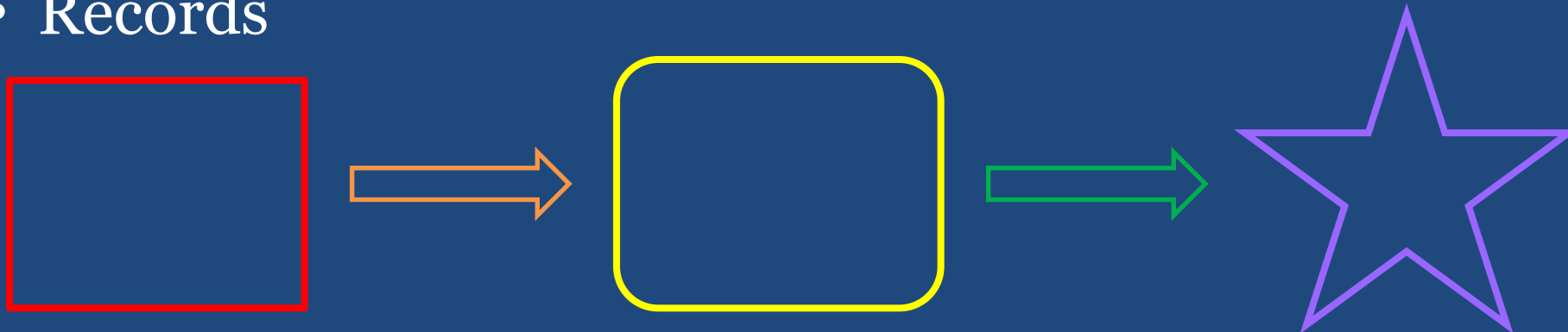
Arrive on site:

- Show credentials and introduction to the most responsible person onsite
- Notice of Inspection/Scope
- Administrative and Jurisdictional Assessment

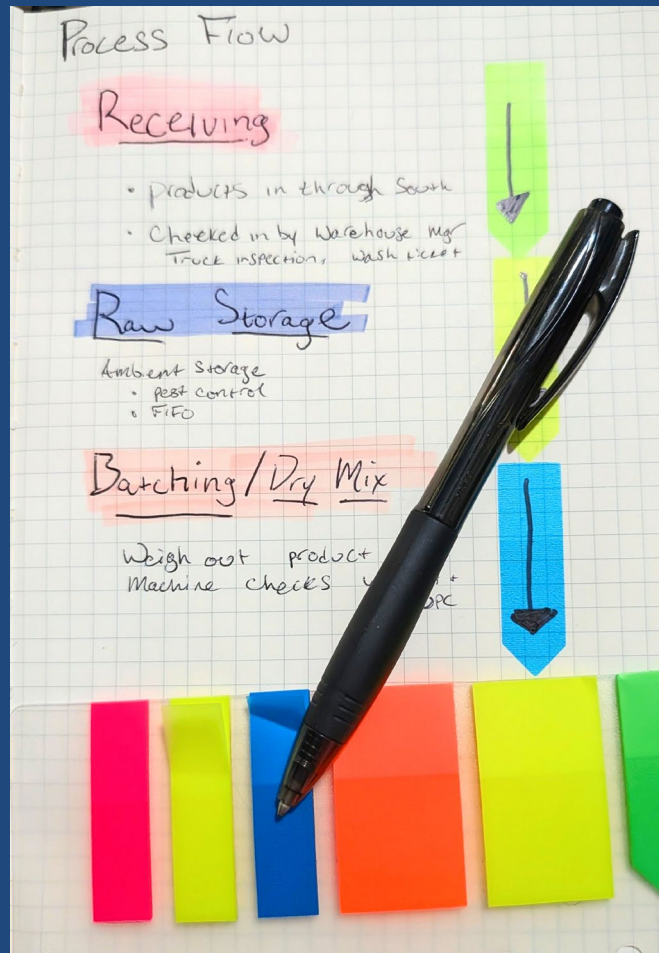
Inspection Process – Walk-Through

Walk-through includes:

- Process flow
- Risk Assessment
- Good Manufacturing Practices
- Evaluation of employee health/hygiene training
- Records

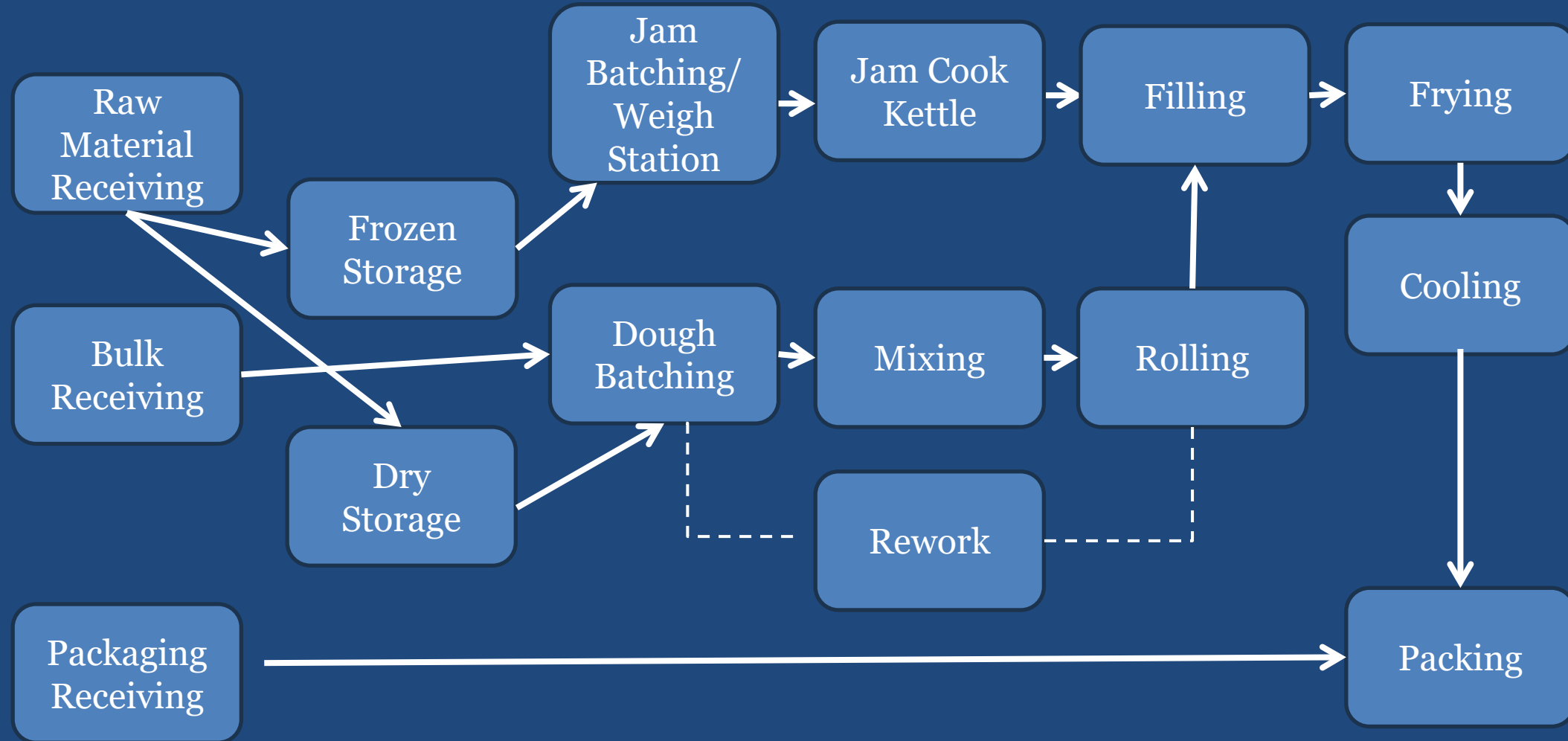


Inspection Process – Process Flows



- Simple
- Process descriptions
- Follows the flow of food

Inspection Process – Process Flows



Inspection Process – Keep in Mind

Additional Discussion Items During Inspection:

- Receiving and storage
- Floor, walls and ceilings
- Types of products manufactured including ready-to-eat (RTE)
- Allergens: Cross-contact and sequencing procedures
- Cleaning and sanitation procedures
- Food additives
- Labeling
- Chemical storage
- Transportation and distribution
- Traceability/lot codes and recalls

Inspection Process – Unique Inspections

Some inspections require specific activities to be performed by the inspector:



Record
Review



Inspection Process – Unique Inspections

Some inspections require specific activities to be performed by the inspector:



Sanitation Activities



Inspection Process – Unique Inspections

Some inspections require specific activities to be performed by the inspector:



Product or
Environmental
Sampling



Inspection Process – Unique Inspections

Some inspections require specific activities to be performed by the inspector:



New Product Review



Inspection Process – Unique Inspections

Some inspections require specific activities to be performed by the inspector:



Land Assessment



Inspection Process – Unique Inspections

Some inspections require specific activities to be performed by the inspector:



Water Source Evaluation



Inspection Process – Unique Inspections

Some inspections require specific activities to be performed by the inspector:



Disaster Response



Where are we at in the process?

- ✓ Arrived on site
- ✓ Introduction – Displayed credentials
- ✓ Explained the scope of the inspection
- ✓ Collected Admin Info and conducted a jurisdictional assessment
- ✓ Walked through the facility including all processing areas and exterior of the buildings and grounds

EXIT INTERVIEW, CLOSEOUT & REPORT WRITING

Poll

Do you perform FDA inspections?

- a) Yes, I work for FDA
- b) Yes, I perform contracted inspections for FDA
- c) No



Drawing to a close

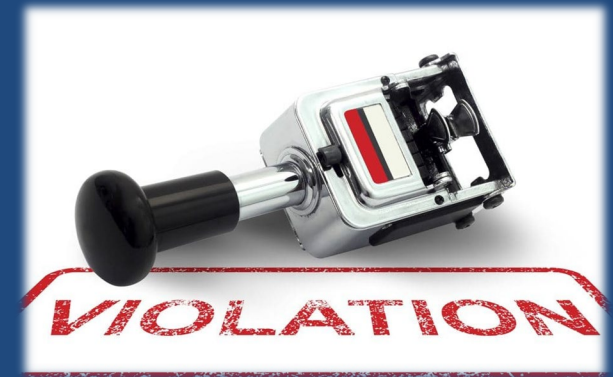
Know your department's policy:

- Are you writing a report onsite?
- What do you leave with the firm?
 - FDA Guidance for Industry
 - Agency Handouts
 - Other relevant information for the firm (cGMPs, Labeling, etc.)
 - 483, 484, or state notice of non-compliance
- Timelines for corrections not completed while on site.

Close out with facility

Wrapping everything up

- Confirm corrections or getting a timeline to complete corrections.
- Who attends the close out?
- Violations/Observations vs Discussion Items
 - Understanding the “why” – discussing Public Health Reasons and rationale for requirements



Report write ups

Reports “tell the story” of the inspection

You are painting as complete a picture as possible

Remember, food safety and compliance with the code are the end goals!



Reports – An Example

What do our reports look like?

- Page one breaks down the CFR into questions
- Selections can be: **IN**, **OUT**, **N/A**, **N/O**
- Overview of findings not the full report

IN = In compliance OUT = Not in compliance N/O = Not observed N/A = Not applicable * = Corrected on site during inspection (COS) R = Repeat Violation

BUILDING AND GROUNDS		
1 Are premises free of harborage which may attract rodents, insects and other pests?	IN	
2 Is adequate drainage provided to avoid contamination of facilities and products?	IN	
3 Is sufficient space provided for the placement of equipment, storage of materials and for production operations?	IN	
4 Are floors, walls and ceilings constructed of easily cleanable materials and kept clean and in good repair?	IN	
5 Are food and food contact surfaces protected from contamination in working areas?	IN	
6 Are food processing areas effectively separated from other operations which may cause contamination of food being processed?	IN	
7 Are food products and processing areas protected against contamination from breakage of light bulbs and other glass fixtures? Is interior lighting sufficient?	IN	
8 Is air quality and ventilation adequate to prevent contamination by dust and/or other airborne substances?	IN	
9 Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests?	IN	
EQUIPMENT AND UTENSILS		
10 Are all utensils and equipment constructed of materials suitable for their intended use and easily cleanable? Is the equipment designed and used in a manner that precludes contamination with lubricants, metal fragments, or other sources? Is the equipment installed and maintained so as to facilitate the cleaning of equipment and adjacent areas?	IN	
11 Is non-food contact equipment in manufacturing or food-handling areas easily cleanable?	IN	
12 Are refrigerator/freezer units equipped with suitable thermometers?	IN	
SANITARY FACILITIES AND CONTROLS		
13 Is the water supply from an approved source and adequate in quantity for its intended uses?	IN	
14 Are the water temperatures and pressures maintained at suitable levels for its intended use?	IN	
15 Is sewage disposed of through a public sewer system and/or an on site sewage disposal system that is operated and maintained according to applicable requirements?	IN	
16 Is the plumbing adequately designed, installed and maintained in a manner to prevent contamination including backflow, back siphonage and cross connection?	IN	
17 Are adequate toilet rooms provided, equipped and maintained clean and in good repair?	IN	
18 Are adequate handwashing facilities provided and supplied with hot and cold water, soap and sanitary towels?	IN	
19 Is all refuse properly stored and protected where necessary from insects, rodents and other pests and disposed of in an adequate manner?	IN	
SANITARY OPERATIONS		
20 Is the facility kept clean and in good physical repair?	IN	
21 Are detergents, sanitizers, hazardous materials and other supplies used in a safe and effective manner, kept in original containers, and stored separate from raw materials?	IN	
22 Are all areas maintained free of insects, rodents, birds and other pests?	IN	
23 Are all utensils and equipment cleaned and sanitized, and at frequent enough intervals to avoid contamination of food products?	IN	
24 Are single use items stored, handled, dispensed, used and disposed of in a manner that prevents contamination?	IN	
25 Are clean utensils and portable equipment stored as so to protect them from splash, dust and other contamination?	IN	
PROCESSES AND CONTROLS		
26 Is responsibility for overall plant sanitation specifically assigned to an individual and are chemical microbiological or extraneous material testing procedures used where necessary to identify sanitation failures or food contamination? Is the facility licensed?	IN	
27 Are raw materials and ingredients adequately inspected and stored to assure that only clean, wholesome materials are used?	IN	
28 Is food processing conducted in a manner to prevent contamination and minimize harmful microbiological growth?	IN	
29 Are packaging processes and materials adequate to prevent contamination?	IN	
30 Are only approved food and/or color additives used?	IN	
31 Are products coded to enable positive lot identification, and are records maintained in excess of expected shelf-life?	IN	
32 Are weighing and measuring practices adequate to ensure the declared quantity of contents?	IN	
33 Are labels of products covered during inspection in compliance (submit violative labels as exhibits)?	IN	
34 Are finished products stored and shipped under conditions which will avoid contamination and deterioration?	IN	
35 Does firm have a HACCP Plan?	N/A	
PERSONNEL		
36 Are personnel with sores, infections, etc., restricted from handling food products?	IN	
37 Do employees wear clean outer garments, use adequate hair restraints and remove excess jewelry when handling food?	IN	
38 Do employees thoroughly wash hands as necessary?	IN	
39 Do employees refrain from eating, drinking and smoking and observe good food handling techniques in processing areas?	IN	
TRANSPORTATION PRACTICES		
40 Are food delivery vehicles clean and in good repair?	IN	
41 Are food stuffs loaded in the same vehicle with toxic chemicals or other potential contaminants?	IN	
42 Are vehicles delivering refrigerated and/or frozen foods equipped to maintain temperatures specified?	IN	

Reports – An Example

Non Violation Comments	
Item Number	Comment
1	Perimeter is well maintained and free of pest harborage conditions.
3	All storage shelves are pulled away from walls allowing for pest inspection. No equipment or food products are being stored on the floor.
7	LED lights are used in all production areas - the lighting in the walk-in-cooler (WIC) has fluorescent tube lighting with a plastic covering.
9	Deliveries of products are received through the front door or the garage style roll up door - both have tight fitting seals allowing now light to pass through.
12	WIC had an ambient temperature of 39 degrees. cream cheese in the reach in cooler registered 36 degrees. All items stored in the three freezers (two standing reach in style, one deep chest style) were frozen solid to touch. All Freezers/Cold Storage are equipped with a temperature continuous monitoring system that triggers mobile alerts to the owner if they go above a designated temperature (40 degrees for coolers, 0 degrees for freezers).
13	Firm uses city water for all production - there is a private well on the premises but it is not plumbed for the production facility and used only in landscape maintenance
14	Water temperature at three compartment sink reached 120 degrees in seconds
18	water at all 3 handsinks reached 100 degrees in under a minute
22	Firm receives biweekly visits from a licensed pest control operator. Most recent visit was 12/18/2025 - no findings of concern were noted
26	Firm owner demonstrated how they test the sanitizer concentration in the three vat sink - it registered approximately 200 ppm which is within the appropriate range for food contact surfaces provided by the chemical manufacturer
35	Firm is considered qualified exempt and does not have a food safety plan nor HACCP plan for their production activities

Inspection Published Comments

- Summaries of activities performed and topics discussed
- Listed handouts provided to firm

Non-Violation Comments

- Each number references a question from pg 1
- Specific information related to that question
- Temperatures taken/discussion items

Inspection Published Comment:

Firm ownership is active and in good standing with KS SOS

Firm is registered with FDA per FURLS and has an up to date QFA on file

During the inspection the firm was producing a variety of baked goods: cinnamon rolls, chocolate chip cookies, "Monster" cookies, white chocolate apricot scones, and blueberry muffins. These items are sold wholesale to local businesses in the area by the pan or the dozen. Baked goods are not individually wrapped - reviewed the ingredients lists provided to each retailer - they appear to be in compliance.

During the inspection the following was either directly observed or explained to the inspector by employees or the person in charge: Sequencing of production to avoid allergen cross contact, Receiving, dry storage, Refrigerated storage, batching, mixing, baking, cooling, packaging, approved suppliers, employee health and hygiene policy and training, continuing training for employees, warewashing, sanitizer testing, pest control, distribution area and delivery practices, lot codes and traceability.

Please refer to the following items sent via email:

Reportable Food Registry - At A Glance

Assessment of Reinspections and Recall Fees by FDA - Fact Sheet

Key Facts about Preventive Controls

Key Requirements: Sanitary Transportation of Human and Animal Food

Key Requirements: Mitigation Strategies to Protect Human Food Against Intentional Adulteration

Key Requirements: Foreign Supplier Verification Programs

Food Safety Preventive Controls Alliance

Provided the following handouts: KSRE MF_3201 Good Manufacturing Practices • #70 Integrated Pest Management • FDA Food Facility Registration Biennial Fact Sheet • KSRE MF_3544 Food Safety Frostings/Fillings • KSRE MF_3385 Food Labeling for Food Producers/Processors

The facility appears to be adequate to operate safely for the products and processes discussed today. Changes to products, processes, or facility may require additional equipment, regulatory approval, and license fee changes. Please contact KDA to review any planned changes to your operation.

Reference/Resource Documents

- IOM – *Chapter 5 for written reports*
- Report Templates
- Class Documents, Trust your training!
- Flipbooks
- Talk with your Team – learn from each other

Key Takeaways - Educate while you Regulate!

- Look for the requirements being met:
 - cGMPs
 - Employee health/hygiene and training programs
 - Records associated with processes, procedures and equipment
 - Ensuring food facility registration as applicable



THANK YOU

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Food Safety and Lodging Program
www.agriculture.ks.gov/FSL