What to Expect During an Inspection

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State of Alaska/Food Safety and Sanitation Program

Purpose

We'll cover expectations to be considered by operators when **preparing for and being inspected by** one of our Environmental Health Officers. This includes:

- Pre-Inspection (Phone)
- Onsite inspection
- Close out
- Possible Follow-up

Pre-Inspection Checklist (Phone)

- These are generally announced
  - State vs FDA Contract Inspections
- Introduce ourselves, determining who the most responsible person is at the facility
- Verify administrative information such as name and address of facility
- Verify the business size, including average annual sales
  - Qualified Facility Attestation status (GMP)
- Discuss status of facility (Bioterrorism Registered)
- Ask, if applicable, what corrective actions were made for observations noted from the previous inspection so we can verify them during the inspection.

Pre-Inspection-Production

- Obtain some basic process and product related information such as:
  - What products are processed at the facility (obtain list of products)
  - If any of the products are ready-to-eat (RTE) or contain allergens
  - The basic flow of the product and process
  - What product(s) will be processed during the inspection

Pre-Inspection-Inspection Schedule

- Inform operator of inspection schedule to include:
  - Walkthrough
  - Evaluation of controls for allergen, sanitation, or process related hazards as applicable
  - Observation of employees performing their duties
  - Records review
  - Close of inspection

ONSITE INSPECTION

- Arrival
  - Request to speak w PIC/owner/QA manager
  - Sign in
  - Introductions and presentation of our credentials and establish jurisdiction
  - Find a place to store items before heading onto the floor

Onsite Inspection

- We'll inquire about specific safety equipment and procedures required, gear up, wash hands
- Determine **what is occurring** (processing, packaging, sanitation, etc.)
- Select **product to follow** for inspection (highest risk, allergens)
- Follow process **flow** throughout the facility typically from receiving to packaging and storage.

Onsite Inspection

- Areas of inspection:
  - Receiving
  - Raw ingredient/packaging storage
  - Processing/Mfg/Packaging
  - Finished product storage/dist.
  - Evaluate design/condition of facility
  - Review records
    - HACCP, FSP, Sanitation Procedures, Allergen Control

Onsite Inspection

- Sanitary Practices/Conditions
  - Facility & Equipment
  - Cleaning/Sanitation Procedures
  - Employee Practices & Health
  - Pest Control
  - Safety of Water
  - Restroom & HW Facilities
  - Waste Mgmt.
  - Prevention of Cross Contact/Contamination
  - Storage, Labeling, Use of Toxic Compound

Significant vs Insignificant

- Significant-potential to affect safety
  - Was it recognized prior or is it ongoing?
  - Corrective actions taken and was record made?
  - Short vs Long term corrections

Corrective Actions

- We'll highlight this item, discuss it with PIC and discuss long/short term corrections
  - Immediate action on:
    - Imminent health hazard
    - Equipment that is found to be unsanitary prior to processing
    - Adulteration (X Contamination, Poor hygiene practices, Critical limits not met)

Monitoring Record Review

- Preventive controls
- Daily Sanitation records
- Corrective Action
- Employee training
- Processing
- Allergen control (as needed)
- Calibration
- Recall plan
- Supply chain program (as applicable)

Monitoring Record Review

- Consumer Complaint Investigation Results
- Product/Environmental Testing Results
- Corrective Actions

Document Collection

- If observations noted we'll request:
  - Photographs
  - Copies of records

Manufactured Food Inspection
Alaska Department of Environmental Conservation
Division of Environmental Health
Food Safety & Sanitation

Permit ID	CFN/ FEI#	Establishment Name	Permit Type	Date
[redacted]	[redacted]	MOTLEY MOO CREAMERY	FP-6 Other Food Processing	3/29/2023
Establishment Mailing Address		**City**	**State**	**Zip**
PO BOX 110556		Anchorage	AK	99511
Physical Location				**Telephone**
11900 Industry WAY UNIT M-8 [redacted]orage, AK 99515				[redacted]
Responsible Party		**Email**		**Person in Charge**
[redacted]		[redacted]		
Purpose of Inspection				
Routine				

IN = in compliance **OUT** = not in compliance **N/O**= not observed **N/A**= not applicable **COS** = corrected on-site during inspection **R**= repeat violation

Compliance Status			COS	R
		Current Good Manufacturing Practices		
		General Provisions		
1.		Qualifications of individuals who manufacture, process, pack, or hold food		
		Current Good Manufacturing Practices		
2.		Personnel		
3.		Plant and grounds		
4.		Sanitary operations		
5.		Sanitary facilities and controls		
6.		Equipment and utensils		
7.		Processes and controls		
8.		Human food by-products		
9.		Mixing of adulterated food		
10.		Storage and transportation		
11.		General record requirements		
		Other Requirements		
12.		Labeling		
13.		Food worker cards		
14.		Hazard Analysis Critical Control Point (HACCP) plan		
15.		Lot records		
16.		Recall procedures		

The following guidance documents have been issued:

		OBSERVATIONS AND CORRECTIVE ACTIONS	
Item Number	**Violation of Code**	**Violations cited in this report must be corrected within the time frames listed below, or as stated in section 18 AAC 31.900(e).**	**Correct By Date**

Inspection Published Comment:
No comment is available.

Visit Date	Received By (Printed Name)	Received By (Signature)	Date	Inspected By	Inspected By (Signature)	Sig. Date	Time In	Time Out
03/29/2023			3/29/2023	Brehan Corveau	Corveau.	3/29/2023	10:30 AM	12:00 AM

Seafood Facility Inspection
Alaska Department of Environmental Conservation
Division of Environmental Health
Food Safety & Sanitation

Permit ID	Establishment Name		CFN/FEI #	
[redacted]	[redacted]		[redacted]	
Establishment Mailing Address	**City**		**State**	**Zip**
[redacted]	Akutan		AK	99553
Physical Location	**City**	**Zip**	**Telephone**	
[redacted]	Akutan	99553	[redacted]	
Responsible Party	**Email**		**Person in Charge**	
[redacted]	[redacted]		[redacted]	
Reason for Inspection	**Permit Type**		**Next Process Date**	**Last Process Date**
FDA Contract	PL-2 Land-Based Processing 5000 or more lbs/day		3/31/2022	3/30/2022
Follow Up Required	**Follow Up Date**		**# Photographs**	
Yes	4/18/2022			

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HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP)

HACCP Plan Documentation			COS	R
1	In	HACCP Plan		
2	In	HACCP Training		
3	In	Plan location and specificity		
4	In	Hazards identified		
5	In	Critical control point(s) (CCP) identified and adequate		
6	In	Critical limit(s) identified and adequate		
7	In	Monitoring procedures adequate and written		
8	Out	Corrective action procedures adequate		
9	In	Verification procedures and frequency adequate		
10	In	Recordkeeping system documents monitoring of CCPs		
11	In	HACCP plan: signed and dated		

HACCP Plan Implementation			COS	R
12	In	Monitoring: Procedures adequately implemented		
13	In	Monitoring: Records kept and accurate		
14	In	Corrective action: Taken and appropriate		
15	In	Corrective actions: Recorded		
16	In	Verfication procedures: Reassessment of HACCP plan		
17	In	Verification procedures: On-going verification activities		
18	In	Verification procedures: Records review		
19	In	Verfication procedures: Corrective actions		
20	In	Verification procedures: Record-keeping		
21	In	Records accurate, retained and available for review		

SANITATION CONTROL

Sanitation Documentation

22	In	Sanitation standard operating procedures (SSOP) written and adequate		

Sanitation Implementation

23	Out	Monitoring: Adequately implemented		
24	In	Monitoring: Records kept and accurate		
25	In	Corrective actions: Taken and adequate		
26	In	Corrective actions: Records maintained and adequate		

GENERAL REQUIREMENTS

General Requirements

27	In	Qualifications, training and supervision		
28	In	Labeling		
29	In	Product standards and testing		
30	In	Recall plan		

The following guidance documents have been issued:

Document Name	Description
FDA Resources for Firms 2022 Handout	Links to all current FDA guidance for Firms 2022, uploaded 12/29/2021

Elements of Written Observations

- The Observation
- Public Health Risk
- Short-term corrective action
- Long-term corrective action
  - Timeline for correction: must be corrected within ten days with an interim measure in place

Close Out

- Meet w PIC to:
  - Discuss each observation on report
  - Communicate findings and solicit CA
  - Discuss other items not in violation
  - Discuss ?'s
  - Sign report

Follow-up

- Possible onsite inspection or
- Sending records/receipts/logs of items

Resources

- Recall Template
- Food Safety Plan Template
  - Cornell FSP Template
  - FDA FSP Builder
- Seafood HACCP Alliance
- FDA Seafood HACCP

Questions

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