

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

158-15 Liberty Ave.
Jamaica, NY 11433
(718) 340-7000 Fax: (718) 662-5661

DATE(S) OF INSPECTION

07/11/2005 - 07/20/2005*

FBI NUMBER

3003189885

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Oleg Marcovich, General Manager

FIRM NAME

Haifa Smoked Fish, Inc.

STREET ADDRESS

94-15 150th St

CITY, STATE, ZIP CODE, COUNTRY

Jamaica, NY 11435-4524

TYPE ESTABLISHMENT INSPECTED

Smoked Fish Processor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Your HACCP plan does not list one or more critical control points that are necessary for each of the identified food safety hazards.

Specifically, your HACCP plan for Refrigerated, vacuum-packaged, cured, cured/smoked ready-to-eat fish does not list processing as a critical control point that is necessary to control pathogen growth. Further you do not have time/temperature controls in place during processing as evidenced by:

- On 7/11/05 throughout the production shift the ambient room temperatures in the evisceration room ranged between 71.8°F to 76.2° F. Fish are routinely in this area for approximately (b) (4) minutes to (b) (4) hour. The temperature of the rinse water after evisceration was 58.8° F and the internal temperature of the fish in the rinse water was 50° F.
- On 7/12/05 throughout the production shift the ambient room temperatures in the slicing/vacuum packing room ranged between 75.2° F to 76.8° F. Temperatures of salmon trimmings were 59.9° F at 11:45 a.m. and salmon trimmings temperatures at 2:50 p.m. were 66.2° F. Trimmings are routinely in room for approximately (b) (4) minutes until bag is full and then placed in refrigerator. Also at 2:56 p.m. we observed 6 x 4oz vacuum packages of sliced raw ready to eat cold smoked salmon were 69.8° F.
- On 7/11/05, ambient temperature in packing area was 78.6° F at 1:45 p.m. while cold smoked sprats were being packed. Packing took approximately .5 hour. At 2:25 p.m. the ambient temperature in the packing area was 79.5° F.

Your HACCP plan for Refrigerated, vacuum-packaged, cured, cured/smoked ready-to-eat fish does not list cooling hot smoked fish as a critical control point that is necessary to control pathogen growth.

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OBSERVATION 2

You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including condition and cleanliness of food contact surfaces, prevention of cross-contamination from unsanitary objects, and exclusion of pests.

The following conditions and practices were observed 7/11/05 and 7/12/05:

Note: These conditions and practices were not reflected in the sanitation monitoring records for either date.

"Equipment and utensils are adequately cleaned"

- Records indicate on 7/10/05 at end of shift a check mark
- Records indicate on 7/11/05 before processing a check mark

Observations made before processing on 7/11/05 included: knife used in vacuum packing/slicing room had dried product residue on blade from previous shift; slicing machine had dried product residue from previous shift and racks used to hang fish on were stacked in processing room and had dried product residue on them from previous use.

"Employee practices do not result in food contamination."

- Throughout inspection employees working in slicing/vacuum packaging room were continuously observed touching waste receptacle, cooler door handle, packaging materials and other equipment while slicing/packing raw ready-to-eat products including escolar and cold smoked salmon --- without changing gloves or sanitizing hands.
- On 7/11/05 at start - up an employee wearing a yellow apron laden with food particles/grime was observed cleaning food contact surfaces and equipment in the evisceration and processing rooms.
- On 7/11/05 during lunch break - employees were observed outside the firm wearing their work uniforms including their rubber processing boots. One worker was observed sitting on the sidewalk curb.
- On 7/12/05 worker was observed in eviscerating room processing lake trout without any head covering.
- On 7/11/05, at 2:00 p.m., worker packing sprats in boxes dropped fish on floor then proceeded to

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pick up fish and put directly in box without washing/cleaning fish.

"Waste is properly stored"

- On 7/11/05 waste basket was observed completely full in processing area next to water cooler at start up. Waste basket was full from previous days shift.
- Refuse was being stored on floor near pallet containing bags of salt used for processing raw ready-to-eat cold smoked products. Flies too numerous to count were observed flying and landing directly on the bags of salt.

"No pests are in the plant!"

- On 7/11/05 flies too numerous to count were observed throughout facility while raw ready-to-eat product was being processed. Fly strips full of dead flies were observed hanging from fixtures in various areas of plant including processing areas.

OBSERVATION 3

Your sanitation control records do not accurately document the conditions or practices observed at your firm.

Specifically, your sanitation records do not accurately document the conditions or practices observed:

- At approximately 7:00 AM, a walk through of the firm found equipment and utensils not cleaned, garbage bin not emptied, and flies throughout the facility. The Daily Sanitation Report dated 7/10/05 for End of Shift Cleaning stated equipment and utensils were adequately cleaned, waste was properly stored and no pests were in plant.
- At approximately 8:00 AM, we observed a male employee performing pre-processing daily sanitation check. The sanitation report for the pre-processing check list stated that there were no deviations from SSOP and corrective actions; however, we observed numerous flies throughout the facility, processing equipment not cleaned from previous shift, waste containers not properly emptied and employees work apparel also not properly cleaned from previous shift.

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OBSERVATION 4

You did not take corrective action that ensured affected product was not entered into commerce and the cause of the deviation was corrected.

Specifically, on 7/12/05, hot smoked mackerel lot "MH191" was cooked at (b) (4) F for approximately 10 minutes. Process schedule/HACCP plan requires hot smoked fish to be cooked at (b) (4) F for a minimum of (b) (4) minutes.

OBSERVATION 5

Appropriate training in food handling techniques and food protection principles has not been provided to food handlers and supervisors.

Throughout inspection employees were observed not handling raw materials or finished ready to eat products as to prevent adulteration. Supervision did not make appropriate corrections unless instructed by FDA personnel.

OBSERVATION 6

Failure to take necessary precautions to protect against contamination of food and food contact surfaces with microorganisms.

Specifically, on 7/11/05 not all necessary precautions to protect against contamination of food and food contact surfaces with microorganisms were taken in the following instances:

- a) We observed three female employees not changing their gloves or sanitizing their hands after touching the waste receptacle, walk-in refrigerator door handle, and packaging materials and equipment while vacuum packing ready-to-eat products such as cold smoked salmon and butterfish.
- b) We observed a male employee cleaning and sanitizing food contact surface in the evisceration room and equipment such as bins and metal racks while wearing a yellow apron laden with food particles and grime.

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OBSERVATION 7

Your process monitoring equipment is not calibrated to ensure that it reads accurately.

Specifically, the following temperatures were observed against an FDA calibrated thermometer:

- Cooler #1 - Brine cooler -
Firm's thermometer on door - 39° F
Firm's monitoring records - 33° F
FDA thermometer - 35.2° F
- Cooler #10 - In process/finished product cooler -
Firm's thermometer on door - 50° F
Firm's thermometer - used for calibration - 44° F
FDA thermometer - 48.8° F
- Cooler #10 on 7/12/05 -
Firm's monitoring records - 36° F
FDA thermometer - 43.5° F

OBSERVATION 8

You did not review some of your critical control point monitoring records within ^{(b) (4)} week of the day that the records are made.

Specifically, your daily temperature log dated 5/27 thru 6/30/05 has no supervisory review. Also, your daily temperature log dated 7/01/05 thru 7/13/05 has no supervisory review signature or date.

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OBSERVATION 9

Failure to remove and adequately cover hand jewelry which cannot be adequately sanitized during periods where food is being manipulated by hand.

Specifically, on 7/12/05 we observed two employees wearing watches while slicing/trimming and then vacuum packaging ready-to-eat cold smoked salmon and cold smoked escolar.

OBSERVATION 10

Employees failed to remove unsecured jewelry or other objects which might fall into food.

Specifically, on 7/12/05 we observed two female employees wearing unsecured and hanging earrings while slicing/trimming then vacuum packaging ready-to-eat cold smoked salmon.

*** DATES OF INSPECTION:**

07/11/2005(Mon), 07/12/2005(Tue), 07/13/2005(Wed), 07/19/2005(Tue), 07/20/2005(Wed)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Joy A. Matthias, Investigator

Andrew F Cohen, Investigator

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Andrew Cohen *Joy A. Matthias*

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