

**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 06/20/2006 - 07/05/2006*
	FEI NUMBER 3003189885

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Arcadi Marcovich, President

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

You did not implement the monitoring, recordkeeping, and verification procedures listed in your HACCP plan.

Specifically, you are not following your monitoring, recordkeeping, and verification procedures that are listed in your HACCP plans for:

- **Cold Smoked Seafood Products**

Monitoring:

A) Brine Cure / Dry Cure CCP

- Your HACCP plan states that you are monitoring the brine strength for (b) (4) batch with a salinometer; however, your daily brining log dated before June 1, 2006 does not indicate the salinometer reading.

B) Cold-Smoke CCP

- Your HACCP plan states that you are monitoring the ambient oven temperature on the process records (temperature recording charts) (b) (4) during processing; however, your temperature recording charts monitor the internal temperature of the fish.

Recordkeeping:

A) Receiving CCP

- HACCP plan states that you will maintain shipper guarantee of proper freezing parameters; however, you are not keeping such records.

B) In-Process Refrigerated Cold Storage CCP / Finished Product Cold Storage CCP

- HACCP plan states you will maintain product temperature log; however, you are not keeping such records.

Verification:

A) Cold Smoke CCP

- Your HACCP plan states that you are calibrating thermometers; however, you do not have any records indicating that your oven thermometers are calibrated.
- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action and verification records; however, your processing records (temperature recording charts) have no signature or date for records dated 6/1/06-6/23/06.

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B) Receiving CCP

- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action and verification records; however, your receiving records have no signature or date.

C) Brining / Dry Curing CCP

- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action and verification records; however, your Daily Thawing and Curing records dated 6/14/06, 6/18/06, 6/19/06, 6/20/06, 6/21/06, 6/22/06, 6/23/06, were reviewed by investigators on 6/26/06 and have no signature or date. Also a review of the firm's Brining / Dry Salting Log dated 11/27/05, 11/28/05, 03/08/06 revealed no signature or date.

• Hot Smoked Seafood Products

Monitoring:

A) Brine Cure / Dry Cure CCP

- Your HACCP plan states that you are monitoring the brine strength for (b) (4) batch with a salinometer; however, your daily brining log dated before June 1, 2006 does not indicate the salinometer reading.

B) Hot-Smoke CCP

- Your HACCP plan states that you are monitoring the ambient oven temperature on the process records (temperature recording charts) (b) (4) during processing; however, your temperature recording charts monitor the internal temperature of the fish.

Recordkeeping:

A) In-Process Refrigerated Cold Storage CCP/ Finished Product Cold Storage CCP

- HACCP plan states you will maintain product temperature log; however, you are not keeping such records.

Verification:

A) Hot Smoke CCP

- Your HACCP plan states that you are calibrating thermometers; however, you do not have any records indicating that your oven thermometers are calibrated.
- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action, and verification records; however, your processing records (temperature recording charts) have no signature or date for records dated 6/1/06-6/23/06.

B) Receiving CCP

- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action and verification records; however, your receiving records have no signature or date.

C) Brining / Dry Curing CCP

- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action and verification records; however, your Daily Thawing and Curing records dated 6/14/06, 6/18/06, 6/19/06, 6/20/06, 6/21/06, 6/22/06, 6/23/06, were reviewed by investigators on 6/26/06 and have no signature or date indicating a review of records have been conducted.

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Also a review of the firm's Brining / Dry Salting Log dated 11/27/05, 11/28/05, 12/26/05, and 03/08/06 revealed no signature or date indicating a review of records.

• **Salt-Cured, Air-Dried Seafood Products**

Monitoring:

A) Brine Cure / Dry Cure CCP

- Your HACCP plan states that you are monitoring the brine strength for (b) (4) batch with a salinometer; however, your daily brining log dated before June 1, 2006 does not indicate the salinometer reading.

Recordkeeping:

A) Receiving CCP

- HACCP plan states that you will maintain shipper guarantee of proper freezing parameters; however, you are not keeping such records.

B) In-Process Refrigerated Cold Storage CCP/ Finished Product Cold Storage CCP

- HACCP plan states you will maintain product temperature log; however, you are not keeping such records.

Verification:

A) Brine Cure / Dry Cure CCP

- Your HACCP plan states that you are calibrating salinometers; however you do not have any records indicating that your salinometers are calibrated.

B) Receiving CCP

- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action and verification records; however, your receiving records have no signature or date.

C) Brining / Dry Curing CCP

- Your HACCP plan states that you will conduct (b) (4) reviews of monitoring, corrective action and verification records; however, your Daily Thawing and Curing records dated 6/14/06, 6/18/06, 6/19/06, 6/20/06, 6/21/06, 6/22/06, 6/23/06, were reviewed by investigators on 6/26/06 and have no signature or date indicating a review of records have been conducted. Also a review of the firm's Brining / Dry Salting Log dated 11/27/05, 12/26/06, 03/08/06 revealed no signature or date

OBSERVATION 2

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

Specifically, you did not take corrective action and did not determine the cause of the deviation as stated in your HACCP plans for Hot Smoked Seafood Products and Cold Smoked Seafood Products.

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- On 6/19/06, you deviated from your critical limit of ambient oven temperature not to exceed (b) (4) °F at the Cold-Smoke Critical Control Point for Cold Smoke Mackerel. The temperature recording chart dated 6/19/06 for lot M164I, M164II, M164III Cold Smoke Mackerel was processed above the minimum temperature at a temperature of 95°F for 6 hrs and 15 minutes. You then shipped the product and did not make a correction to the process and took NO corrective action.
- On 5/21/06, you deviated from your critical limit of product must reach a minimum internal temperature of (b) (4) °F for a minimum continuous time of (b) (4) minutes at the Hot-Smoke Critical Control Point for Hot Smoked Whitefish. The temperature recording chart dated 5/21/06 for lot WFH 138 Hot Smoked Whitefish was processed at the maximum temperature of (b) (4) °F for only 15 minutes. You then shipped the product and did not make a correction to the process and took NO corrective action.
- On 3/9/06, you deviated from your critical limit of product must reach a minimum internal temperature of (b) (4) °F for a minimum continuous time of (b) (4) minutes at the Hot-Smoke Critical Control Point for Hot Smoked Paddlefish. The temperature recording chart dated 3/9/06 for lot PFH 61 Hot Smoked Paddlefish was processed at a maximum temperature of 140°F. You then shipped the product and did not make a correction to the process and took NO corrective action.
- On 11/13/05, you deviated from your critical limit of product must reach a minimum internal temperature of (b) (4) °F for a minimum continuous time of (b) (4) minutes at the Hot-Smoke Critical Control Point for Hot Smoked Seabass. The temperature recording chart dated 11/13/05 for lot SBH 313 Hot Smoked Seabass was processed at a maximum temperature of 120°F. You then shipped the product and did not make a correction to the process and took NO corrective action.
- Your HACCP plan for Hot Smoked Seafood Products indicates that at your Brine Cure Step, cooler temperature is not to exceed (b) (4) °F for a maximum continuous time not to exceed (b) (4) hours. Your Daily Temperature Log for 6/22/06 indicates a temperature reading of 46°F for cooler #8 which is above the critical limit. This cooler temperature record for 6/22/06 was signed and dated by management with no corrective action indicated on the record.

OBSERVATION 3

You do not have a written HACCP plan that outlines controls for a food safety hazard that is reasonably likely to occur.

Specifically, your firm does not have a written HACCP plan for ready-to-eat whole (gutted) Herring in Brine (vacuum packed) and ready-to-eat Herring in Oil to control the hazards of Clostridium Botulinum, parasites, and histamine.

OBSERVATION 4

Your records do not include the name and location of the processor or importer and signature and initials of the person performing the operation.

Specifically, the firm's smoke processing records for cold and hot smoked seafood products (temperature recording charts) dated 6/1/06-6/23/06 does not include the name and location of the processor; and does not detail the signature and initials of the person performing the operation.

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OBSERVATION 5

Your monitoring records do not contain the actual values and observations obtained during monitoring.

Specifically, your cooler and freezer calibration temperatures are not recorded. In practice, an employee compares the temperature of a handheld thermometer to the temperature of the coolers and freezers and does not record the actual value of the temperature; but places a check mark on the temperature calibration log.

OBSERVATION 6

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, protection of food, food packaging material, and food contact surfaces from adulteration, and proper labeling, storage and use of toxic chemicals.

Specifically, the following sanitation conditions and practices were observed prior to and during processing on 6/20/06; however, they were not included on sanitation monitoring records dated 6/19/06 and 6/20/06:

Condition and Cleanliness of Food Contact Surfaces:

You are not monitoring the cleanliness of your food contact surfaces as evident by:

- After cleaning and prior to processing product residues were observed:
 - a) Three (3) pieces of salmon roe were observed on the production table in front of the small production scale in the equipment storage/salmon roe repackaging area.
 - b) Fish residue was observed on small production scale used to weigh finished product (ready-to-eat cold smoked salmon and caviar) located on production table in the equipment storage/salmon roe repackaging area.
 - b) Production knife used for slicing ready-to-eat cold smoked salmon was stored with product residue on the stainless steel knife blade where the knife handle meets the blade which was stored under the large production scale on production table in the equipment storage/salmon roe repackaging area.
 - c) Three (3) pieces of fish residue were observed underneath small production scale after an employee removed the scale from the production table located in the equipment storage/salmon roe repackaging area.
 - d) Fish residue was observed behind the large scale on production table located in the equipment storage/salmon roe repackaging area.
 - e) Liquid residue was observed on top of metal caviar can sealer cart located next to production table in the equipment storage/salmon roe repackaging area.
 - f) Fish residue was observed on outside of thawing bin located in the main processing room in front of the eviscerating room.
 - g) Dry product residue was observed in between two cutting boards on the eviscerating production table in the eviscerating room. The top cutting board was being used to fillet mackerel

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- h) Fish residue inside (b) (4) production knife holder on the wall next to the (b) (4) sink in the eviscerating room.
- i) Fish residue observed in between cutting board production table top and (b) (4) bracket (which holds the cutting board to the table) located in the packaging room.
- j) Fish residue was observed on ban saw blade in the non-kosher production area. Management stated that the last time the saw was used was last week.
- k) Fish residue was observed on door handle to smoker oven #5 in the non-kosher room.
- l) Fish residue and residue build up observed on thermometer probe in smoker oven #5 Management stated that the last time that oven was used to smoke fish was last week.
- m) Fish residue on vacuum machine used to package hot smoke paddlefish located in the non kosher area. Management stated that the last time the vacuum package machine was used was last week.

Protection from Adulterants:

You are not monitoring protection from adulterants as evident by:

- Roll of white paper used to line the production tables in the packaging room was observed stored on top of a metal cart and directly touching and absorbing clear liquid that was on top of the metal cart. The cart was located in the packaging in between the sink and the vacuum package machine.
- An employee was observed using a high pressured hose to clean the production aprons which are used by employees in the eviscerating room. The spray from the hose was observed to be hitting the floor and splashing onto bags of salt stored on a pallet next to the eviscerating room.

Proper labeling, storage, and use of toxic compounds:

You are not monitoring proper labeling and use of toxic compounds as evident by:

- On 6/20/06, it was observed that the sanitizer ((b) (4)) used by your firm to sanitize food contact surfaces (knives, table tops, slicers, etc.), floors, walls, and drains was not operating at the concentration of (b) (4) ppm. This was observed as management attempted to check the concentration of the sanitizer by performing titration tests on the sanitizer three times and all three tests were inconclusive.
- A barrel of (b) (4) % aqueous stabilized (b) (4) and a barrel of (b) (4) Disinfectant did not have any legible product labels to identify contents of barrels.

OBSERVATION 7

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.

Specifically, on 6/20/06 the following were observed throughout the processing area:

- Broken floor tile with standing water observed on the floor in the drying room next to the packaging room.
- Broken and chipped wood molding on the bottom right corner of the entrance into the eviscerating room where fish

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residue, standing water, and apparent mold growth was observed.

- Dry fish residue was observed on the floor in cooler #10 which is used for packaging ready-to-eat product.
- Fish residue on floor next to pallet of raw material salt located in the main processing room next to eviscerating room.
- Bases of the fans located on the floor in drying room used for drying ready-to-eat product were observed to be covered in rust and fish residue also observed on the floor.

OBSERVATION 8

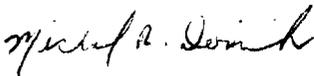
Your HACCP plan was not signed and dated upon modification.

Specifically, your HACCP plans for Cold Smoked Seafood Products, Hot Smoked Seafood Products, Salt-Cured, Air-Dried Seafood Products, Smoked Fish Salad Products were reviewed and revised January, 2006; however, were not signed and dated.

*** DATES OF INSPECTION:**

06/20/2006(Tue), 06/21/2006(Wed), 06/22/2006(Thu), 06/26/2006(Mon), 06/27/2006(Tue), 06/28/2006(Wed), 06/29/2006(Thu), 07/05/2006(Wed)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:


Michael R. Dominick, Investigator


Joyce A. Williams, Microbiologist


Patty P. Kaewussdangkul, Microbiologist


Charisse K. Green, Investigator

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