

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 341-7000 Fax: (718) 662-5561	09/13/2005 - 10/07/2005
	FBI NUMBER
	3003189885

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

FIRM NAME	STREET ADDRESS
Haifa Smoked Fish, Inc.	94-15 150th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jamaica, NY 11435-4524	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 have not implemented your monitoring, recordkeeping and verification procedures that are listed in your HACCP plan for refrigerated, vacuum packaged, cured, cured/smoked ready-to-eat fish as follows:

Monitoring:

A) Bining - CCP

- Your HACCP plan states that you are monitoring the salinometer readings; however, you do not have any monitoring records indicating so.

B) Smoking/drying/cooking - CCP

- Your Critical Limits included on your HACCP plan state your Production Log and recorder charts monitor the smokehouse temperature and time in the smokehouse for cold smoking; however, your temperature recorder charts monitor the internal temperature of the fish during the smoking critical control point.
- In addition your HACCP plan states that the firm is monitoring the critical limits for hot smoking and cold smoking processing with recorder charts, however it was observed that your processing was not adequately monitored as evident by the following:

a) The temperature recording chart dated 9/22/05 lot SL258 cold smoked salmon is illegible. The pen recorder marking on the recording chart does not enable you to accurately determine the temperature of the cold smoked salmon during processing in the oven.

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		10/07/2005

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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

b) The temperature recording chart dated 9/13/05 lots M248I, II, and III (cold smoked mackerel) was placed in smoker (to record) at 8:20 am. Temperature recording chart reads process started at 8:00 am, when in fact product was placed in smoker at 5:30 am.

c) The temperature recording chart dated 9/13/05 lots WFC248II, WFC249I and WFC249II (cold smoked whitefish) was placed on smoker (to record) at 8:25 am. Chart reads process started at 8 am when in fact product was placed in smoker to process at 5:30 am.

d) You did not keep temperature recording charts for the processing of lots M248I, II, and III (cold smoked mackerel) on 9/13/05 from the hours between 5:30 am and 8:20 am.

e) You did not keep temperature recording charts for the processing of lots WFC248III, WFC249I, and WFC249II (cold smoked whitefish) on 9/13/05 from the hours between 5:30 am and 8:25 am.

f) There is no temperature recording chart or production log for the processing of lots SL236.

Recordkeeping:

A) Packaging/labeling - CCP

- Your HACCP plan states that you are keeping a packing log. In practice you are not keeping a packing log.

Verification:

A) Smoking/drying/cooking - CCP

- Your HACCP plan states that your temperature recording devices (thermometers) are calibrated (b) (4). In practice your temperature recording devices used in your smoking ovens have not been calibrated for approximately 2 years.

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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

- Your HACCP plan states that you are reviewing your brining records (b) (4) a week. In practice on your Brining logs the supervisor signs and dates when the product starts the brining process; however, there is no supervisory review with signature and date documenting the actual length of time product is in brine.

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 during the following instances:

- The temperature recording chart dated 9/12/05 lot PF248 hot smoked Paddlefish was processed under the minimum critical limit temperature of (b) (4) F.
- The temperature recording chart dated 9/12/05 lots SL251 and SL251I cold smoked Salmon were both processed above the maximum critical limit temperature of (b) (4) F.
- The temperature recording chart dated 9/13/05 lot SL251II cold smoked Salmon was processed above the maximum critical limit temperature of (b) (4) F.
- The temperature recording chart dated 9/8/05 lots CPC250 cold smoked Capelin and WFC245II cold smoked Whitefish were both processed above the maximum critical limit temperature of (b) (4) F.

OBSERVATION 3

Your review of critical control point monitoring records does not ensure that the records are complete and verify that they document values that are within critical limits.

Specifically, your Smoking (Production) log records do not contain actual values for smoke schedule start/finish. Records also do not contain actual values for the temperature of the smoke chamber for cold smoke fish and the internal temperature of the fish for hot smoke fish.

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Smoked Fish Processor

OBSERVATION 4

Your HACCP plan does not list verification procedures and frequencies that have been developed to ensure that the HACCP plan is adequate to control food safety hazards, and is being effectively implemented.

Specifically, your HACCP plan for refrigerated, vacuum-packaged, cured, cured/smoked ready-to-eat fish does not list verification procedures at the brining step as follows:

- a) At the brining step documentation of process establishment to achieve a minimum of (b) (4)% water phase salt is not listed.
- b) Specifically, cooler and freezer calibration temperatures are not recorded. In practice, an employee uses a hand held thermometer, which is not NSIT-traceable and compares the ambient temperature of the cooler/freezer to the (b) (4) thermometer reading on the outside of the cooler. The employee does not record the temperature, but places a check mark on the Temperature Calibration Log indicating calibration of the thermometer.

OBSERVATION 5

You did not review some of your calibration records within a reasonable time after the records were made.

Specifically, your firm's Temperature Calibration log covering the thermometers/thermocouples in your refrigerators and freezers used for raw material storage, brining, thawing, and finished product storage, is not being reviewed, signed and dated by supervision.

OBSERVATION 6

Your HACCP plan does not list the food safety hazards that are reasonably likely to occur.

Specifically, your firm's HACCP plan for refrigerated, vacuum-packaged, cured, cured/smoked ready-to-eat fish such as mackerel, herring, and escolar, does not list the food safety hazard of histamine at the finished product storage step.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	FBI NUMBER
TO: Arcadi Marcovich, President	3003 39685

FIRM NAME	STREET ADDRESS
Haifa Smoked Fish, Inc.	94-15 150th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jamaica, NY 11435-4524	Smoked Fish Processor

OBSERVATION 7

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 insanitary objects, and protection of food, food packaging material, and food contact surfaces from adulteration.

Specifically, the following sanitation conditions and practices were observed during processing on 9/13/05; however, they were not included on sanitation monitoring records dated 9/12/05 and 9/13/05:

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) Fish residue was observed on the table next to the slicing machine in the packing/slicing room.
 - b) Hanging racks that were used the previous day were stored on the floor in the refrigerator with physical residue on them. The racks were used to hang mackerel on during cold smoking.

Prevention of Cross Contamination:

You are not monitoring the prevention of cross contamination as evident by:

- An employee was observed packaging ready to eat cold smoked salmon trout. While packaging the product, the employee licked his right hand then proceeded to open a plastic bag used to vacuum package the product. Without using any hand sanitation, the employee immediately picked up the ready to eat cold smoked salmon trout to place in the plastic bag.

Protection from Adulterants:

You are not monitoring protection from adulterants as evident by:

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- In the refrigerator #1:
 - a) Exposed wiring and hanging tape on the condenser located on the refrigerator ceiling was observed above uncovered pails of exposed raw herring fillets and a tank of uncovered/exposed defrosting raw capelin.
 - b) In various areas dried product residue and fresh product residue was observed on the refrigerator floor.
- In walk-in refrigerator #3:
 - a) Walls located inside the refrigerator were in disrepair exhibiting rust in various areas, while products such as mackerel were brining.
 - b) Caulking hanging from ceiling in refrigerator while mackerel was brining in tank below.
- In packing/slicing room, finished product (ready to eat cold smoked salmon sides) was being trimmed and packed on table next to window frame with peeling paint and exposed raw wood.
- Throughout the inspection high pressure hoses in the main processing area were being used to rinse equipment and floors during processing. The spray from these hoses was observed hitting the floor and splashing onto equipment including smoke racks, brine totes, and thaw tanks containing mackerel and whitefish.

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TYPE ESTABLISHMENT INSPECTED

Smoked Fish Processor

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:



Andrew F. Cohen, Investigator

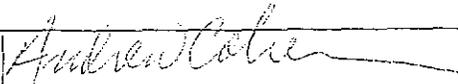


Michael R. Dominick, Investigator



Charisse K. Green, Investigator

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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 have not implemented your monitoring, recordkeeping and verification procedures that are listed in your HACCP plan for refrigerated, vacuum packaged, cured, cured/smoked ready-to-eat fish as follows:

Monitoring:

A) Brining - CCP

- Your HACCP plan states that you are monitoring the salinometer readings; however, you do not have any monitoring records indicating so.

B) Smoking/drying/cooking - CCP

- Your Critical Limits included on your HACCP plan state your Production Log and recorder charts monitor the smokehouse temperature and time in the smokehouse for cold smoking; however, your temperature recorder charts monitor the internal temperature of the fish during the smoking critical control point.
- In addition your HACCP plan states that the firm is monitoring the critical limits for hot smoking and cold smoking processing with recorder charts, however it was observed that your processing was not adequately monitored as evident by the following:
 - a) The temperature recording chart dated 9/22/05 lot SI.258 cold smoked salmon is illegible. The pen recorder marking on the recording chart does not enable you to accurately determine the temperature of the cold smoked salmon during processing in the oven.

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b) The temperature recording chart dated 9/13/05 lots M248I, II, and III (cold smoked mackerel) was placed in smoker (to record) at 8:20 am. Temperature recording chart reads process started at 8:00 am, when in fact product was placed in smoker at 5:30 am.

c) The temperature recording chart dated 9/13/05 lots WFC248II, WFC249I and WFC249II (cold smoked whitefish) was placed on smoker (to record) at 8:25 am. Chart reads process started at 8 am when in fact product was placed in smoker to process at 5:30 am.

d) You did not keep temperature recording charts for the processing of lots M248I, II, and III (cold smoked mackerel) on 9/13/05 from the hours between 5:30 am and 8:20 am.

e) You did not keep temperature recording charts for the processing of lots WFC248III, WFC249I, and WFC249II (cold smoked whitefish) on 9/13/05 from the hours between 5:30 am and 8:25 am.

f) There is no temperature recording chart or production log for the processing of lots SL236.

Recordkeeping:

A) Packaging/labeling - CCP

- Your HACCP plan states that you are keeping a packing log. In practice you are not keeping a packing log.

Verification:

A) Smoking/drying/cooking - CCP

- Your HACCP plan states that your temperature recording devices (thermometers) are calibrated (b) (4). In practice your temperature recording devices used in your smoking ovens have not been calibrated for approximately 2 years.

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- Your HACCP plan states that you are reviewing your brining records (b) (4) a week. In practice on your Brining logs the supervisor signs and dates when the product starts the brining process; however, there is no supervisory review with signature and date documenting the actual length of time product is in brine.

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 during the following instances:

- The temperature recording chart dated 9/12/05 lot PF248 hot smoked Paddlefish was processed under the minimum critical limit temperature of (b) (4) F.
- The temperature recording chart dated 9/12/05 lots SL251 and SL251I cold smoked Salmon were both processed above the maximum critical limit temperature of (b) (4) F.
- The temperature recording chart dated 9/13/05 lot SL251II cold smoked Salmon was processed above the maximum critical limit temperature of (b) (4) F.
- The temperature recording chart dated 9/8/05 lots CPC250 cold smoked Capelin and WFC245II cold smoked Whitefish were both processed above the maximum critical limit temperature of (b) (4) F.

OBSERVATION 3

Your review of critical control point monitoring records does not ensure that the records are complete and verify that they document values that are within critical limits.

Specifically, your Smoking (Production) log records do not contain actual values for smoke schedule start/finish. Records also do not contain actual values for the temperature of the smoke chamber for cold smoke fish and the internal temperature of the fish for hot smoke fish.

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Jamaica, NY 11435-4524	Smoked Fish Processor	

OBSERVATION 4

Your HACCP plan does not list verification procedures and frequencies that have been developed to ensure that the HACCP plan is adequate to control food safety hazards, and is being effectively implemented.

Specifically, your HACCP plan for refrigerated, vacuum-packaged, cured, cured/smoked ready-to-eat fish does not list verification procedures at the brining step as follows:

- a) At the brining step documentation of process establishment to achieve a minimum of (b) (4) % water phase salt is not listed.
- b) Specifically, cooler and freezer calibration temperatures are not recorded. In practice, an employee uses a hand held thermometer, which is not NSIT-traceable and compares the ambient temperature of the cooler/freezer to the (b) (4) thermometer reading on the outside of the cooler. The employee does not record the temperature, but places a check mark on the Temperature Calibration Log indicating calibration of the thermometer.

OBSERVATION 5

You did not review some of your calibration records within a reasonable time after the records were made.

Specifically, your firm's Temperature Calibration log covering the thermometers/thermocouples in your refrigerators and freezers used for raw material storage, brining, thawing, and finished product storage, is not being reviewed, signed and dated by supervision.

OBSERVATION 6

Your HACCP plan does not list the food safety hazards that are reasonably likely to occur.

Specifically, your firm's HACCP plan for refrigerated, vacuum-packaged, cured, cured/smoked ready-to-eat fish such as mackerel, herring, and escolar, does not list the food safety hazard of histamine at the finished product storage step.

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CITY, STATE, ZIP CODE, COUNTRY Jamaica, NY 11435-4524	TYPE ESTABLISHMENT INSPECTED Smoked Fish Processor	

OBSERVATION 7

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 insanitary objects, and protection of food, food packaging material, and food contact surfaces from adulteration.

Specifically, the following sanitation conditions and practices were observed during processing on 9/13/05; however, they were not included on sanitation monitoring records dated 9/12/05 and 9/13/05:

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) Fish residue was observed on the table next to the slicing machine in the packing/slicing room.
 - b) Hanging racks that were used the previous day were stored on the floor in the refrigerator with physical residue on them. The racks were used to hang mackerel on during cold smoking.

Prevention of Cross Contamination:

You are not monitoring the prevention of cross contamination as evident by:

- An employee was observed packaging ready to eat cold smoked salmon trout. While packaging the product, the employee licked his right hand then proceeded to open a plastic bag used to vacuum package the product. Without using any hand sanitation, the employee immediately picked up the ready to eat cold smoked salmon trout to place in the plasti bag.

Protection from Adulterants:

You are not monitoring protection from adulterants as evident by:

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TYPE ESTABLISHMENT INSPECTED

Smoked Fish Processor

- In the refrigerator #1:
 - a) Exposed wiring and hanging tape on the condenser located on the refridgerator ceiling was observed above uncovered pails of exposed raw herring fillets and a tank of uncovered/exposed defrosting raw capelin.
 - b) In various areas dried product residue and fresh product residue was observed on the refrigerator floor.
- In walk-in refrigerator #3:
 - a) Walls located inside the refrigerator were in disrepair exhibiting rust in various areas, while products such as mackerel were brining.
 - b) Caulking hanging from ceiling in refrigerator while mackerel was brining in tank below.
- In packing/slicing room, finished product (ready to eat cold smoked salmon sides) was being trimmed and packed on table next to window frame with peeling paint and exposed raw wood.
- Throughout the inspection high pressure hoses in the main processing area were being used to rinse equipment and floors during processing. The spray from these hoses was observed hitting the floor and splashing onto equipment including smoke racks, brine totes, and thaw tanks containing mackerel and whitefish.

*** DATES OF INSPECTION:**

09/13/2005(Tue), 09/14/2005(Wed), 09/16/2005(Fri), 09/20/2005(Tue), 09/21/2005(Wed), 09/22/2005(Thu), 09/23/2005(Fri), 09/27/2005(Tue), 09/28/2005(Wed), 09/30/2005(Fri), 10/03/2005(Mon), 10/07/2005(Fri), 10/17/2005(Mon)

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Smoked Fish Processor

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:



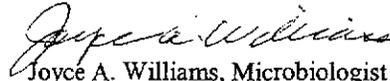
Andrew F. Cohen, Investigator



Michael R. Dominick, Investigator



Charisse K. Green, Investigator



Joyce A. Williams, Microbiologist

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