

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

152-15 Liberty Ave.
Jamaica, NY 11433
(718) 340-7000 Fax: (718) 662-5661

DATE(S) OF INSPECTION

06/22/2004 - 06/24/2004

FBI NUMBER

3003189885

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Arcadi Marcovich, President

FIRM NAME

Haifa Smoked Fish

STREET ADDRESS

9415 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 do not have a written HACCP plan that outlines controls for a food safety hazard that is reasonably likely to occur.

Specifically, you do not have a written HACCP plan for the following:

- a) Vacuum packed cold smoked Golden Brook Trout to control the hazard of Clostridium botulinum and pathogen growth. . Further, you do not have controls in place for the processing and storage of this product. Examples of your lack of controls for these hazards are evidenced by:
 - You do not monitor or have records to show that the product was not temperature abused during processing and storage.
 - The product is not stored on ice and you do not have continuous monitoring of your finished product cooler.
- b) Air packed cold smoked Golden Brook Trout to control the hazard of pathogen growth. . Further, you do not have controls in place for the processing and storage of this product. Examples of your lack of controls for these hazards are evidenced by:
 - You do not monitor or have records to show that the product was not temperature abused during processing and storage.
 - The product is not stored on ice and you do not have continuous monitoring of your finished product cooler.

OBSERVATION 2

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 6/23/04 the temperature in the eviscerating room was 68.9°F, the temperature of the rinse water after

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Arcadi Marcovich *William D. DeTager*

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evisceration was 54.5°F, and the internal temperature of the fish in the rinse water 50°F. Fish remain in this area for approximately 3 hours before they are placed in a brine solution. They are then brined for (b) (4) days in a cooler. On 6/24/04, the temperature of the cooler was taken with an FDA calibrated thermometer and was 48° F and the temperature of the brine was 42° F.

- On 6/23/04 racks of cold smoked mackerel were in the packaging area. Temperatures of the fish on the racks ranged from 46.2° to 50.5°F at 8:10a.m. Packaging of these fish was completed at 9:45 and the last pallet was taken to just outside the cooler area. That pallet remained outside the cooler until 2:45p.m. Ambient temperatures in that area were 66°F and the internal temperature of the fish was 62°F.
- On 6/23/04 at 7:30a.m. a rack of cold smoked capelin was in the main processing area awaiting packaging. It was packaged at 10:30a.m. and the internal temperature of the fish was 66°F. After boxing it was moved to an area just outside the cooler. It remained in this area until 2:45p.m., the internal temperature of the fish was 66°F.
- On 6/23/04 at 9:00a.m. box of vacuum packed, cold smoked salmon was placed at the loading dock awaiting shipment. The ambient air temperature was 70.2°F. This box remained in this area, unrefrigerated, until at least 12:30p.m.
- Dried salt - cured Whitefish is air dried in an unrefrigerated room for several days. On 6/24/04, the ambient temperature of the room was 52° F and the internal temperature of the fish ranged between 68° F and 70° F.
- Dried salt - cured Capelin is air dried in an unrefrigerated room for several days. On 6/24/04, the ambient temperature of the room was 52° F and the internal temperature of the fish ranged between 68° F and 70° F.

OBSERVATION 3

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 not determine the cause of the deviation during the following instance:

- The temperature recording chart dated 6/22/04 lots #M168 (mackerel) and #WFC169 (whitefish) both cold smoked products were processed above the maximum critical limit temperature of (b) (4) F.

OBSERVATION 4

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

Specifically, your HACCP plan for refrigerated vacuum packed cured, cured/smoked ready-to-eat fish does not list the food safety hazard of Clostridium botulinum at the brining, smoking, and finished product storage steps and histamine at the finished product storage step. In practice these hazards are not controlled as evidenced by the following examples:

- The brine strength is not formulated to achieve the required (b) (4) salinity. The most recent results of water phase salt analysis showed ranges from 2.5% to 10.07%
- A box containing vacuum packed cold smoked salmon was left on the loading dock for at least 3-1/2 hours at

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- c) Cooler storage for vacuum packed and air packed finished product ranged between 38°F to 48°F as taken with an FDA calibrated thermometer.

OBSERVATION 5

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

Specifically, you are not implementing your monitoring procedures that are listed in your HACCP plan for refrigerated, vacuum packaged, cured, cured/smoked ready-to-eat fish as follows

- a) Brining
 - Your HACCP plan states that you are monitoring and recording your brine strength and time in brine. In practice you are monitoring your brine strength but not recording it. Additionally you are not recording the time product is put in brine and the time product is taken out of the brine.
- b) Storage of finished product
 - Your HACCP plan states that you monitor the cold storage temperature (b) (4). In practice you check cooler temperatures daily and verbally give those values to an employee for computer entry.

OBSERVATION 6

Your HACCP plan does not list a critical limit that ensures control of one or more hazards and lists a critical limit that does not ensure control of one or more hazards.

Specifically, the critical limit at the brining and smoking critical control points does not ensure control of Clostridium botulinum or pathogen growth as follows:

- a) Brining
 - Your HACCP plan lists a critical limit of brine strength and times as per process schedule. A standard operating procedure that is attached to the HACCP plan lists other critical factors for brining including fish to brine ratio and temperature of brining if the brining time is in excess of (b) (4) hours. In practice you are determining minimum brine strength with a salinometer not according to your process schedule, you are recording the brine dates but not the brine time, and you are not monitoring or recording the fish to brine ratio or temperature of the brine. For example:
 - 1) According to your scheduled process the brine strength for cold smoked mackerel is (b) (4) and the brine time is for a minimum (b) (4) hours. On 6/23/04, an employee measured the brine strength to 30° and latter changed it to 50° neither of which met the process schedule of (b) (4).
 - 2) According to your standard operating procedure if the brine time is over (b) (4) hours it must be conducted under refrigeration at (b) (4) F or below. On 6/24/04 the brine temperatures ranged between 38° F and 45° F on a calibrated FDA thermometer.

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OBSERVATION 7

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 and smoking steps as follows:

- a) At both the brining and smoking/drying steps documentation of process establishment to achieve a minimum of (b) (4) % water phase salt is not listed.
- b) At the brining step, water phase salt analysis is not listed. In practice, you have water phase salt analysis performed (b) (4). The most recent lab report for water phase salt dated 2/27/04 lists water phase salt values ranging from as low as 2.57 to as high as 10.07.

OBSERVATION 8

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

Specifically, on 6/24/04 the following temperatures were observed against an FDA calibrated thermometer:

	FDA Therm	(b) (4) Therm
Brine cooler	48° F	42° F
Brine/product cooler	44° F	42° F
Finished product cooler	34° F	38° F

Note: Your daily temperature checks ranged from 35° F to 40° F. on 6/24/04

Your procedure is to calibrate your cooler thermometers to your (b) (4) scale thermometer, which is not NSIT-traceable. Further, you do not perform a calibration, you perform a comparison.

OBSERVATION 9

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

Specifically, you do not write actual values of brine strength and calibration of thermometers as follows:

- a.) Brine strength
 - Brine strength is recorded on a sticky note that is attached to each temperature recording chart. The value that

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is recorded is the process value and not the actual value of the brine strength.

- b) Cooler and freezer calibration temperatures are not recorded. In practice, an employee compares the temperature of an (b) (4) thermometer to the temperature of the cooler, does not record the actual value, but instructs another employee to input that the cooler and freezers have been calibrated.

OBSERVATION 10

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, your records are computer generated and do not include the name and location of the processor or importer and the signature and initials of the person performing the operation.

OBSERVATION 11

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

Specifically, your brining, smoking and finished product storage records are not reviewed and dated as being reviewed.

OBSERVATION 12

Your HACCP plan lists verification frequencies that have not been developed in accordance with 21 CFR 123.8(a) to ensure that your 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 lists (b) (4) wps checks. In practice you reportedly do wps analysis (b) (4).

OBSERVATION 13

You do not have or have not implemented written verification procedures and product specifications for ensuring that fish you import are processed in compliance with the Seafood HACCP regulation.

Specifically, you do not have written verification procedures and product specifications for frozen herring and frozen mackerel that you directly import from (b) (4).

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OBSERVATION 14

You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including exclusion of pests.

The following conditions and practices were observed 06/22/04 and 06/23/04:

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

Safety of water

- a) You are not monitoring the safety of water as evidenced by:
- There are no backflow prevention devices on hose bibs in the main processing area. These hoses were submerged in thaw tanks.

Condition and Cleanliness of Food Contact Surfaces:

- a) You are not monitoring the condition of your food contact surfaces as evidenced by:
- Cutting boards in the evisceration room and packing/slicing room are gouged and had visible product residue in the gouges. These cutting boards cannot be cleaned. Raw, ready-to-eat cold smoked fish (salmon, mackerel, butterfish, trout etc.) and cooked ready-to-eat hot smoked fish come in direct contact with these boards during processing.
 - Knives used in the evisceration and packing/slicing room have wooden handles. These knife handles cannot be cleaned. Employees using these knives were in direct contact with raw ready-to-eat and cooked ready-to-eat products.
- b) You are not monitoring the cleanliness of your food contact surfaces as evidenced by:
- Processing aprons are stored at the end of the day and during breaks on unlearned equipment such as totes, smoking racks, walls and on drums. These aprons are not cleaned and sanitized and are worn by employees who are in direct contact with raw ready-to-eat and cooked ready-to-eat products.
 - Plastic strip curtains between the eviscerating and main process area are broken, gouged and stained. These curtains cannot be cleaned. These curtains were observed in direct contact with raw fish that was later to be processed as cold smoked fish - a raw ready-to-eat product.
 - After cleaning and prior to processing product residues were observed:
 - 1) Underneath cutting board
 - 2) A skinner, slicer and knives (this equipment is used to process raw ready-to-eat and cooked ready-to-eat products).

Prevention of Cross Contamination:

- a) You are not monitoring the prevention of cross contamination as evidenced by:
- An employee was observed dropping a side of salmon on the floor in the main processing area. He then picked it up from the floor and returned it to the thaw tank. Salmon is typically processed as raw, ready-to-eat, cold smoked salmon.

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- Hoses with visible filth and residue that are routinely dragged across the floor and are not cleaned and sanitized are submerged in thaw tanks and in direct contact with product that is processed as raw ready-to-eat.
- Employees were observed handling hoses that were previously on the floor and then were observed handling product that was either in process to be raw ready-to-eat or already processed as cooked ready-to-eat product. These employees did not wash or sanitize their hands or their gloves.
- An employee was observed outside the building handling a trash container and then was observed touching raw ready-to-eat product without washing and sanitizing his hands or gloves.
- An employee touched unclean and unsanitized faucet handle, pallet jack, and hose that had been on floor and then returned to process raw, ready-to-eat product without washing and sanitizing his hands or gloves.
- An employee was observed picking up plastic bags (from the thaw tank) from the floor, touching the handle to the freezer and cooler, and then touching the plastic strip curtains. He then went back to touching raw, ready-to-eat product without washing and sanitizing his hands or gloves.
- An employee packing raw, ready-to-eat and cooked ready-to-eat smoked fish was observed touching an uncleaned and unsanitized pallet jack handle and cooler door and then touching raw ready-to-eat and cooked ready-to-eat product without washing and sanitizing his hands or gloves.
- Several employees handling raw ready-to-eat product were observed routinely touching unclean and unsanitized surfaces including cooler handles, pallet jacks, faucet handles, spray bottles, etc. with without washing and sanitizing his hands or gloves.
- Raw, ready-to-eat smoked salmon on a rack being removed from the cooler was observed in direct contact with the door frame of the cooler - an unclean and unsanitized surface.
- An employee was observed rinsing his apron on the floor and then hanging it on a smoking rack to dry overnight. These aprons are not cleaned and sanitized before use and are in direct contact with in process, raw, ready-to-eat product.
- Totes used for brining and thawing products that are eventually processed as raw, ready -to-products are washed on the floor in the main process area. They are tipped on their side and rinsed with a high pressure hose. The splash from the floor was observed going inside the tote.

Protection from Adulterants

- a) You are not monitoring protection from adulterants as evidenced by:
- High pressure hoses are used to rinse equipment and floors at the end of the day. The spray from these hoses was observed hitting the floor and splashing onto equipment including smoke racks, brine totes, and thaw tanks. This equipment is not cleaned and sanitized before use.
 - Unlabeled bottles containing unidentified liquids that may have been cleaners, sanitizers, or degreasers were observed in the packing/slicing, eviscerating, and main processing area.

Exclusion of pests

- a) You are not monitoring exclusion of pests as evidenced by:
- Flies were observed in the eviscerating, packing/slicing, shipping and main processing area. The flies were observed landing on product contact surfaces including totes, aprons, and boxes.

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OBSERVATION 15

Your HACCP plan was not signed and dated at least annually.

Specifically, your HACCP plan for refrigerated, vacuum-packaged, cured, cured/smoked ready-to-eat fish is not dated.

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Andrew F Cohen, Investigator

Debra D. Devlieger, Investigator

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