DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/13/2023-7/17/2023* FEI NUMBER 1000208659

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joel E. Alexander, Office Manager

FIRM NAME	STREET ADDRESS
Ocho Rios-Miami, Inc.	3675 NW 71st St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Miami, FL 33147-6525	Warehouse

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 I OBSERVED:

OBSERVATION 1

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

This is a repeat observation from the previous inspection(s) conducted on 12/02/2022 and 03/09/2021.

Specifically, your HACCP Plan for Salted Herring and Salted Mackerel, lists monitoring procedures of "Temperature in the truck/container", "Check thermometer record for temperature reading of delivery container", and "Receiving record to include copy of invoice with thermometer record attached-date and time recorded" at the Receiving CCP. These monitoring, recordkeeping, and verification procedures are not being implemented as each shipment is received with a Data Logger USB that must be downloaded upon receipt; however, these records are not being printed, maintained or verified within (b) (4) of preparation. Data logger printout for last incoming shipment received on (b) (4) was printed during the inspection on 07/13/2023. Record for shipment received on (b) (4) does not include continuous temperature monitoring from throughout the shipment.

OBSERVATION 2

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

This is a repeat observation from the previous inspections conducted on 05/06/2021 and 07/09/2021.

Specifically, your HACCP Plan for Salted Herring and Salted Mackerel does not list the food safety hazard of pathogenic bacteria growth and toxin formation as a result of time and temperature abuse at

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Anabel Veiga, Investigator X Anabel Veiga Investigator Signed By: 2002194464 Date Signed: 07-17-2023 13:55:44	7/17/2023

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the CCP's of Receiving and Storage for Vacuum Packed Split Mackerel observed in storage in warehouse cooler on 07/13/2023. Additionally, the HACCP Plan has not been signed and dated as reviewed at least annually.

OBSERVATION 3

You did not conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product you process.

This is a repeat observation from the previous inspection conducted on 03/17/2022.

Specifically, your firm has not conducted a hazard analysis to determine whether there are food safety hazards associated with the seafood products your firm receives, warehouses, and distributes. Refrigerated Salted Cod and Salted Pollack include Pathogenic Bacteria Growth as a result of time and temperature abuse. These Seafood products were observed stored in your refrigerated area of the warehouse on 07/13/2023 and were received on (b) (4) under Bill of Lading # (b) (4).

OBSERVATION 4

You did not review your critical control point monitoring records within one week after the records were made.

Specifically,

a) The continuous temperature monitoring records that are printed (b) (4) for the walk-in cooler are not reviewed within (b) (4) of the day that the records are made for records between 03/31/2023 – 07/06/2023.

b) The (b) (4) visual temperature checks of the walk-in cooler and the freezer are not reviewed within (b) (4) of the day that the records are made for records between 07/07/2021 – 07/10/2023.

OBSERVATION 5

You do not maintain records of calibration of process-monitoring instruments.

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This is a repeat observation from the previous inspection conducted on 12/20/2022.

Specifically, your firm did not provide any calibration records for your continuous temperature monitoring system. This continuous temperature monitoring system is used to monitor the firm's main cooler and freezer used for Storage CCP(b)(of refrigerated/frozen seafood products before distribution to customers. The firm's HACCP Plan for Salted Herring and Salted Mackerel states that the calibration for the continuous temperature monitoring system, will be conducted(b) (4) and recorded in binder.

***DATES OF INSPECTION**
7/13/2023(Thu), 7/17/2023(Mon)

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