

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 6/10/2025-6/24/2025*			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Brian (nmi) Li, Manager		FEI NUMBER 3009909783			
FIRM NAME MIN JIANG FOOD STORE INC DBA KOI KOI TRADING		STREET ADDRESS 2710 Yates Ave			
CITY, STATE, ZIP CODE, COUNTRY Commerce, CA 90040-2624		TYPE ESTABLISHMENT INSPECTED Fresh salmon processor and seafood 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 WE OBSERVED: OBSERVATION 1 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, I observed the following sanitation and cGMP deviations during the establishment inspection (EI) while you were processing fresh aquacultured imported salmon, lot number (b) (4) processed on 06/10/2025 and lot number (b) (4) processed on 06/17/2025, imported from (b) (4) and intended for raw consumption per your HACCP plan titled "HACCP Plan for Fresh Filleting Non Scombroid Fish Products - (Raw Consumption)": <u>Conditions and Cleanliness of Food Contact Surfaces</u> - On 06/10/2025, I observed organic fish-like material on tools such as knives and knives sharpening steels used in processing fresh aquacultured imported salmon intended for raw consumption post cleaning and sanitation after conducting my own pre-op monitoring check. The knives are a food contact surface (FCS) and used to filet fresh aquacultured imported salmon intended for raw consumption. Additionally, the knives sharpening steels contact the blade of said knives which make the (b) (4) steel a FCS. - On 06/10/2025, I observed rust-like material on knives sharpening steels located in the fresh fish processing room. Knife blades contacted these knives sharpening steels and the same knives were used in processing fresh aquacultured imported salmon intended for raw consumption. - On 06/11/2025, I observed an employee handling and processing fresh aquacultured imported salmon drop their knife on the fresh fish processing room floor, pick-up the same knife, rinse the same knife with water from (b) (4) nozzle attached to (b) (4) water hose observed hanging on the top lip of a gray waste barrel, and continued handling and processing fresh aquacultured imported salmon without washing his hands, sanitizing his hands, and changing gloves. - On 06/11/2025, I observed an employee handling and processing fresh aquacultured imported salmon place a fresh					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Phillip J Sample, Investigator Emily D Lam, Investigator Caspar N Heys, Investigator </td> <td style="width: 40%; text-align: center; vertical-align: bottom;"> DATE ISSUED 6/24/2025 Phillip J Sample Investigator Signed By: 2002133764 Date Signed: 06-24-2025 14:34:24 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Phillip J Sample, Investigator Emily D Lam, Investigator Caspar N Heys, Investigator	DATE ISSUED 6/24/2025 Phillip J Sample Investigator Signed By: 2002133764 Date Signed: 06-24-2025 14:34:24
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salmon head in a gray waste barrel, then this same employee reached their gloved hand into the same gray waste barrel and pick-up the same fresh salmon head and the same employee placed the fresh salmon head on cutting board (b) (4). Next, the same employee placed the same fresh salmon head into a transparent plastic poly bag to be sold and/or distributed by your firm. The employee did not wash their hands, sanitize hands, or change gloves after touching the interior of the gray waste barrel which displayed signs of filth.

- On 06/18/2025, I observed a firm employee conduct a pre-operational sanitation check in the fresh fish processing room. According to your "Fillet Room (b) (4) Cleaning Schedule" record, all areas and equipment in the fresh fish processing room were identified as acceptable. However, upon further inspection, I observed fish scales on employee aprons and organic fish-like material between the (b) (4) backsplash and (b) (4) cutting board on (b) (4). Employee aprons and the area mentioned above on (b) (4) come in contact with fresh aquacultured imported salmon intended for raw consumption.

Prevention of Cross-Contamination from Insanitary Objects

- From 06/10/2025 through 06/11/2025, I observed heavily soiled plastic curtains with rips, tears, and unidentified foreign material at the entrance/exit to (b) (4). Additionally, from 06/10/2025 through 06/11/2025, I observed employees contact these same plastic curtains with their gloved hands when transferring fresh aquacultured imported salmon from the (b) (4) to the fresh fish processing room. These same employees did not wash their hands, sanitize their hands, or change gloves and continued to handle fresh aquacultured imported salmon intended for raw consumption. Additionally, I observed these same employees (b) (4) plastic aprons contact these same plastic curtains at the entrance/exit to (b) (4). Additionally, on 06/17/2025, I observed these same plastic curtains heavily soiled with rips, tears, and unidentified foreign material at the entrance/exit to (b) (4).
- From 06/10/2025 through 06/11/2025, I observed heavily soiled blue plastic swinging doors with unidentified foreign material at push points located at the entrance/exit to the fresh fish processing room. Additionally, from 06/10/2025 through 06/11/2025, I observed employees contact these same blue plastic swinging doors with their gloved hands when transferring fresh aquacultured imported salmon from the (b) (4) to the fresh fish processing room. These same employees did not wash their hands, sanitize their hands, or change gloves after touching the blue plastic swinging doors and continued to handle fresh aquacultured imported salmon intended for raw consumption. Additionally, I observed these same employees blue plastic aprons contact these same blue plastic swinging doors to the entrance/exit to the fresh fish processing room. Additionally, on 06/17/2025, I observed these same blue plastic swinging doors heavily soiled with unidentified foreign material at push points located at the entrance/exit to the fresh fish processing room.
- From 06/10/2025 through 06/11/2025, I observed employees handling and processing fresh aquacultured imported

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salmon intended for raw consumption in the fresh fish processing room while hanging (b) (4) water hose nozzles with build-up of what appeared to be organic fish-like material on the top lips of gray waste barrels which were not a clean and sanitary surface. These same (b) (4) water hose nozzles are used to rinse cutting boards and fresh aquacultured imported salmon intended for raw consumption. Additionally, these same employees did not wash hands, sanitize hands, and change glove after handling the (b) (4) nozzles and continued to handle and process fresh aquacultured imported salmon intended for raw consumption. - From 06/10/2025 through 06/11/2025, I observed employees handling and processing fresh aquacultured imported salmon in the fresh fish processing room. These same employees were observed rinsing out the interior surface of Styrofoam containers used for packing fresh aquacultured imported salmon intended for raw consumption. I observed one Styrofoam container being rinsed on its side on a (b) (4) pallet; I observed one Styrofoam container being rinsed on its side and contacting an employee's boot; I observed one Styrofoam container being rinsed on its side and contacting the fresh fish processing room floor. I observed employees place fresh aquacultured imported salmon processed filets intended for raw consumption into these same Styrofoam containers with no packaging such as a transparent plastic poly bag. - From 06/10/2025 through 06/11/2025, I observed an employee handling and de-scaling fresh aquacultured imported salmon in the fresh fish processing room. This same employee was observed moving (b) (4) pallets outside of the fresh fish processing room. Upon entrance to the fresh fish processing room, the employee did not wash their hands, sanitize their hands, change their gloves and continued to de-scale fresh aquacultured imported salmon intended for raw consumption. <u>Protection of Food, Food Packaging Material, and Food Contact Surfaces from Adulteration</u> - On 06/10/2025 while monitoring post processing cleaning and sanitation, I observed back-splash and/or over-spray of water from (b) (4) water hoses contact the floor causing water droplets to land on transparent plastic poly bags used to pack fresh aquacultured salmon filets intended for raw consumption. Additionally, these same transparent plastic poly bags were being stored in the fresh fish processing room in (b) (4) with evidence of unidentified foreign material build-up on the exterior and interior surfaces. This is a repeat observation from the previous inspection(s) conducted on 03/12/2020 (written observation).			
OBSERVATION 2 You do not have a written HACCP plan that outlines controls for a food safety hazard that is reasonably likely to occur. Specifically, on 06/10/2025, you stated your firm receives (b) (4)			
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(b) (4) (b) (4) (b) (4) You do not have a HACCP plan to control refrigerated storage temperatures to address the histamine hazard for fresh tuna portions received (b) (4). On 06/10/2025, you stated the fresh tuna portions received (b) (4) are not opened upon receiving at your firm and you do not conduct temperature monitoring checks on fresh tuna portions at receiving.			
OBSERVATION 3 You did not implement the monitoring and recordkeeping procedures listed in your HACCP plan. Specifically, your HACCP plan titled "HACCP Plan for Fresh Filleting Non Scombroid Fish Products - (Raw Consumption)" dated 10/01/2024 identifies a critical control point (CCP) for undeclared major food allergens (fish) at the finished product labeling step also known as CCP (b) (4). According to this same HACCP plan, you will create, conduct, and maintain CCP records for "Record of review of finished product labels" per this same HACCP plan. On 06/11/2025, I requested allergen finished product label monitoring records and you stated you do not have an allergen monitoring record in place to monitor for CCP (b) (4). You do not have the appropriate CCP (b) (4) finished product label monitoring records on file per this same HACCP plan regarding allergens, specifically species of fish and common market name. This is a repeat observation from the previous inspection(s) conducted on 03/12/2020 (written observation).			
OBSERVATION 4 You do not have or have not implemented an affirmative step for ensuring that fish you import are processed in compliance with the Seafood HACCP regulation. Specifically, your written procedure titled "Standard Operating Procedures - Vendor Certification Policy for Listeria monocytogenes in Imported Ready to Eat Seafood Products by Koi Koi Trading" dated 10/01/2023 has not been implemented. On 06/11/2025, I requested records and documentation mentioned in this same procedure such as laboratory testing results for pathogens, food allergen safety program for labels, copy of seafood HACCP program on file, and product specifications, letter of guarantee, and direct or third-party audits for fresh aquacultured salmon varieties from countries that do not have a memorandum of understanding (MOU) for fish and fishery products with the United States of America. During the FDA inspection, I observed Styrofoam containers with fresh salmon originating in the (b) (4) which does not have an MOU with the United States of America for fish and fishery products. You do not have the appropriate records and/or documents on file.			
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This is a repeat observation from the previous inspection(s) conducted on 03/12/2020 (written observation).

OBSERVATION 5

Your verification procedures do not include, at a minimum, ongoing verification activities including review of monitoring, corrective action, and calibration records.

Specifically, on 06/11/2025, I reviewed thermometer calibration records from 02/03/2025 to 05/31/2025 which revealed numerous deviations of thermometer actual value readings against an (b) (4) used to obtain temperatures of fresh aquacultured imported salmon at the receiving step also known a CCP (b) (4) You did not implement or document corrective actions when thermometer calibration monitoring checks exceeded (b) (4) degrees Fahrenheit per the standard of (b) (4) degrees Fahrenheit against a (b) (4) thermometer and your thermometer calibration procedure which lists (b) (4) degrees Fahrenheit actual values as acceptable. Additionally, on 06/11/2025, you stated you thought the standard thermometer calibration range was from (b) (4) degrees Fahrenheit to (b) (4) degrees Fahrenheit. Also, you stated you obtain temperatures of fresh aquaculture imported salmon with an (b) (4) thermometer of the outer surface of the fresh salmon at CCP (b) (4) to obtain temperature readings at receiving. This temperature monitoring method does not align with checking temperatures of the inner most portion of fresh fish per the Fish and Fishery Products Hazards and Controls Guidance.

***DATES OF INSPECTION**

6/10/2025(Tue), 6/11/2025(Wed), 6/17/2025(Tue), 6/18/2025(Wed), 6/20/2025(Fri), 6/24/2025(Tue)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."