

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 2/19/2026-2/20/2026 FEI NUMBER 3004273032	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kohji Yamamoto, Manager			
FIRM NAME JFC International, Inc		STREET ADDRESS 631 Southwestern Blvd Ste 100	
CITY, STATE, ZIP CODE, COUNTRY Coppell, TX 75019-7009		TYPE ESTABLISHMENT INSPECTED Warehouse ambient, refrigerated and frozen	
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 take corrective action that ensured affected product was not entered into commerce and the cause of the deviation was corrected. Your facility imports Reduced Oxygen Packaging (ROP) refrigerated fresh fish from Japan, including products in. Your HACCP plan identifies <i>Clostridium botulinum</i> as a hazard for ROP products and establishes a critical limit of (b) (4) during receiving to control this hazard. Your HACCP plan also establishes critical limits for refrigerated fresh fish products at temperature do not exceed (b) (4). Your written procedures require that suppliers be discontinued when (b) (4) placement issues are identified until the issue has been corrected. During the inspection conducted on 02/19-20/2026, a review of receiving records for seafood products revealed the following: 1. (b) (4) readings documented temperatures exceeding established critical limits during transport, yet products were accepted without adequate corrective actions or hazard evaluation 2. (b) (4) were marked as "pass" despite documented temperature excursions above critical limits			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Cristina Alicea Matos, Investigator Ryan Nguyen, Investigator Cristina Alicea Matos Investigator Signed By: Cristina Alicea Matos - Date Signed: 02-20-2026 13:54:06 X	
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3. Products were "conditionally accepted" based on endpoint checks without proper evaluation of time-temperature abuse during transit
4. Your firm did not follow written procedures requiring discontinuation of suppliers with (b) (4) placement issues

Additionally, your receiving records do not clearly identify which products are ROP versus non-ROP packaging, making it difficult to verify that appropriate critical limits are being applied.

ROP Products

1. (b) (4) - Invoice # (b) (4) (ROP Product):
 - (b) (4) # (b) (4) (ROP) and # (b) (4) (Non-ROP) were logged as "fail" as temperatures were above (b) (4) during transport.
 - (b) (4) # (b) (4) showed temperatures above (b) (4) for approximately 24 hours during transportation. The products included in the shipment included Mackerel, Sea Urchin, Yellowtail, Alfonsino and Trevali.
 - (b) (4) # (b) (4) (ROP product) - the products included in the shipment included Alfonsino, Sea Urchin, Red Seabream and Fresh Hiram. The (b) (4) showed temperatures above (b) (4) (exact duration cannot be calculated as the temperature chart does not provide detailed information).
 - Also, temperatures for the fish show the received fish temperatures were at (b) (4) for ROP product and (b) (4) for non-ROP product

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Despite both (b) (4) being marked as "fail," there is no documentation of product rejection or adequate corrective action addressing the significant time-temperature abuse for this ROP product where <i>C. botulinum</i> is the identified hazard 2. (b) (4) - Invoice # (b) (4) (ROP Product): list of seafood products? (b) (4) # (b) (4) for Non-ROP (move to non ROP section) product was marked as "pass" even though temperatures were documented as over (b) (4) for most of the trip. (b) (4) records was not available for review during the inspection Product was "conditionally passed" with justification: "product and cooling media were found in good condition and temperature was in established range" Additionally, temperature for one of the ROP products was (b) (4) (above the established (b) (4) limit) and was accepted without further investigation. The (b) (4) for this product was not evaluated during transportation. No documented corrective action or hazard evaluation for accepting ROP product above the critical limit temperature for <i>C. botulinum</i> were included. Non ROP products 1. (b) (4) - Invoice # (b) (4). The products included in the shipment included: Barracuda, Bluefin Searobin, Gizzard Shad, Sea urchin, Seabream, Amberjack. (b) (4) shows temperatures above (b) (4) for 9 hours during transit your limit is (b) (4) during transit. Product was "conditionally accepted" with justification: "incorrect (b) (4) placement" and "temperature of the fish under (b) (4)"					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Cristina Alicea Matos, Investigator Ryan Nguyen, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> DATE ISSUED 2/20/2026 Cristina Alicea Matos Inves Igalor Signed By: Cristina Alicea Matos - Date Signed: 02-20-2026 13:54:06 </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Cristina Alicea Matos, Investigator Ryan Nguyen, Investigator	DATE ISSUED 2/20/2026 Cristina Alicea Matos Inves Igalor Signed By: Cristina Alicea Matos - Date Signed: 02-20-2026 13:54:06
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This product did not have a (b) (4)

No documented hazard evaluation regarding the 9-hour temperature excursion

Your firm did not discontinue use of the supplier until the (b) (4) misplacement issue was corrected, contrary to your corrective action written procedure identified in their HACCP plan for fresh fish non-histamine

2. (b) (4) - Invoices # (b) (4). The product included in the shipment was Fresh Farmed Bluefin Tuna fillets (histamine producing)

(b) (4) # (b) (4) showed temperatures above critical limits for 4+ hours. Your temperature monitoring records do not provide sufficient information regarding the time and temperatures that product exceeded the critical limit

As per your corrective action memo, the justification documented: "(b) (4) was at the bottom of the box under products"

Despite the documented temperature excursion, the (b) (4) was recorded as "pass" and product was received

(b) (4) information was not saved or available for review during the inspection

No corrective action documentation addressing the critical limit deviation

3. (b) (4) - Invoice # (b) (4). The shipment included bluefin Tuna farm raised (histamine producing).

(b) (4) # (b) (4) was logged as "pass" even though the (b) (4) showed temperatures above (b) (4) throughout all transportation of the product

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Exact amount of time cannot be calculated as the temperature chart does not provide detailed information

Product was "conditionally passed" with justification: "product and cooling media were found in good condition and the temperature was in established range"

No documented evaluation of the continuous temperature excursion during the entire transit period

Your firm did not discontinue use of the supplier until the (b) (4) misplacement issue was corrected, contrary to your written procedure

4. (b) (4) - Invoice # (b) (4) (ROP Product). The shipment included Trout, Seabream, Yellowtail and Hirame (flounder).

(b) (4) # (b) (4) for Non-ROP product was marked as "pass" even though temperatures were documented as over (b) (4) for most of the trip.

In addition, you explained that the refrigerated seafood products temperatures are taken by placing a thermometer (b) (4), and internal temperatures for the fish are not taken.

X Ryan Nguyen
Investigator
Signed By: 2004837574
Date Signed: 02-20-2026 13:55:05

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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."