DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/24/2025-3/3/2025* FEI NUMBER 3001237297

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Philip K. Sinz, Owner/CEO

FIRM NAME	STREET ADDRESS
Northwest Frozen LLC	2141 S 211th St Ste G
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Des Moines, WA 98198-5179	Frozen Sushi Manufacturer

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 and verification procedures listed in your HACCP plan.

Specifically, the document titled Food Safety Plan for Frozen Sushi dated 02/01/2025 includes the Process Preventive Control of Pathogen growth due to time-temperature abuse on page 25. It states the Storage Cooler has a critical limit of (b) (4) as (b) (4) perishables are stored there and the Prep Cooler has a critical limit of (b) (4) The temperature is monitored with manual checks and a continuous monitoring device. Manual checks are recorded (b) (4) using a (b) (4) device.

A. Continuous monitoring in the Prep Cooler from 06/19/2024-06/27/2024 are recorded on the document called "Prep Cooler". On 06/19/2024, there is a comment that says, "Probe Removed" and no temperature records are shown in the Prep Cooler until the probe was replaced on 06/27/2024. There was no increased monitoring with manual checks while the continuous monitoring device was out of service. The Prep Cooler was not monitored over (b) (4) as employees were not present on those days. On 06/21/2024, a temperature in the Prep Cooler was recorded as (b) (4) at 3:20 PM. The corresponding note says, "On defrost mode. Product moved to storage cooler". There was no further assessment to ensure product in the cooler was kept at a safe temperature or that the storage cooler returned to an appropriate temperature. The next temperature in the Prep Cooler was recorded on 06/24/2024 at 4:04 AM as (b) (4) The document Cold Storage Program – SOP 047 dated 03/16/2022 states on page 7 that when a nonconformance of Prep Cooler temperature (b) (4) occurs, (b) (4) (b) (4)

B. Continuous monitoring records for the Prep Cooler from 06/27/2024-07/09/2024 showed 6 instances when the temperature exceeded the critical limit of (b) (4) for over one hour. A table summarizing these values is below:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Indigo A Doll, Investigator X Indigo A Doll Investigator Signed By: 2003173553 Date Signed: 03-03-2025 09:46:09	3/3/2025

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Date and Time Temperature (b) (4)	Date and Time Temperature	Time Cooler Exceeded (b) (4)	Maximum Temperature Recorded (b) (4)
06/27/2024 13:11	06/28/2024 08:56	9 hr 45 min	(b) (4)
06/28/2024 17:41	06/29/2024 12:31	13 hr 50 min	
06/29/2024 19:01	07/01/2024 08:06	13 hr 5 min	
07/01/2024 09:11	07/01/2024 14:56	5 hr 45 min	
07/08/2024 14:41	07/08/2024 18:11	3 hr 30 min	
07/08/2024 19:01	07/08/2024 21:16* *measurements on 07/08/2024 at 20:21 and 20:26 measured (b) (4) and (b) (4) respectively	2 hr 15 min* *exception of up to 15 min when temp measured between (b) (4) and (b) (4)	

The document Storage Temperature Log 012 dated 06/24/2024-07/09/2024 shows temperatures manually recorded using the (b) (4) A summary of the recorded values in the Prep Cooler are below:

Date and Time of Recording	Prep Cooler Temperature (b) (4) (b) (4)	Comments/Corrective Actions Noted
06/27/2024 04:03	(b) (4)	
06/27/2024 16:35		

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X Indigo A Doll Investigator Signed By: 2003173553 Date Signed: 03-03-2025 09:46:09

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06/28/2024 04:02	(b) (4)
06/28/2024 15:32	
07/01/2024 04:00	

Prep cooler activities include (b) (4) The temperature monitoring device and (b) (4) in this cooler are separated from the mixing area by a wall and an open doorway. (b) (4) sushi filling is stored in (b) (4) in either the storage cooler or the prep cooler until they are used in production of Ready to Eat (RTE) sushi products in the adjacent (b) (4) room. Mixing activities typically occur from (b) (4) and the (b) (4) (b) (4) The contents of the (b) (4) (b) (4) ingredients which require refrigeration to control the growth of pathogens.

C. On 12/05/2024 at 04:30 AM, the Storage Temperature Log 012 dated 12/03/2024-12/11/2024 documents a temperature of (b) (4) in the storage cooler. This temperature exceeds the critical limit of (b) (4) in the Storage Cooler as the (b) (4) (b) (4) seafood product surimi is stored in this cooler. There are no comments on the log related to the breach of the critical limit. I reviewed the continuous monitoring temperatures in the storage cooler from 12/03/2024-12/05/2024 and observed (b) (4) temperatures were recorded below the critical limit of (b) (4)

D. The document Food Safety Plan for Frozen Sushi dated 02/01/2025 includes the Process Preventive Control of Pathogen growth due to time-temperature abuse on page 25. It states the temperature is monitored with manual checks and a continuous monitoring device. Manual checks are recorded (b) (4) using a (b) (4) device. Storage Temperature Log 012 dated 01/24/2025-02/08/2025

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and 02/22/2025-02/26/2025 showed the temperature of coolers was recorded only (b) (4) on 01/26/2025-01/29/2025, 02/02/2025, 02/04/2025, 02/06/2025, and 02/25/2025.

E. Storage Temperature Log 012 and continuous monitoring temperatures are reviewed and verified over (b) (4) from the first record. Storage Log 012 is reviewed after the (b) (4) for example, the log dated 01/24/2025-02/08/2025 was signed as verified on (b) (4) from the first measurement recorded on 01/24/2025. The document Cold Storage Program – SOP 047 dated 03/16/2022 states on page 3, (b) (4) (b) (4) (b) (4) No written verification of continuous monitoring data review is recorded to ensure storage temperature critical limits are not exceeded.

F. Thermometers used to monitor the storage temperature hazards are not calibrated on an (b) (4) basis. The continuous monitoring device is verified with an (b) (4) (b) (4) and calibrated as needed only if (b) (4) verification checks show a temperature difference of (b) (4) The last (b) (4) verification of continuous monitoring devices occurred on 01/02/2025 and all (b) (4) data loggers measured a temperature of (b) (4)

G. Continuous monitoring probes in the Storage Cooler and Prep Cooler are located (b) (4)

OBSERVATION 2

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

Specifically,

A. The (b) (4) film used to hermetically seal some sushi products - including Banzai Spicy Crab Roll, Banzai

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Shrimp and Avocado Roll, Banzai California Roll, (b) (4) (b) (4) - have an (b) (4) This rate is less than the 10,000 cc/m^s/24 hours required to control for *Clostridium botulinum* (*C. bot*) growth. The hazard of *C. bot* growth due to the use of Reduced Oxygen Packaging (ROP) is not identified in the Hazard Analysis steps "Adding packets and lidding/sealing" or "Packing and Labeling" on page 21 of document Food Safety Plan for Frozen Sushi dated 02/01/2025. Finished product labels for Banzai Spicy Crab Roll, Banzai Shrimp and Avocado Roll, Banzai California Roll, (b) (4) (b) (4) are printed as "KEEP FROZEN".

B. The document Receiving, Shipping, and Product Release Program – SOP 045 dated 12/18/2023 states that upon receipt, the surface temperature of perishable raw materials are measured using an (b) (4) thermometer. It states (b) (4) (b) (4) and (b) (4) Surimi is received (b) (4) The Hazard Analysis step "Receiving: Perishable food ingredients" on page 15 of document titled Food Safety Plan for Frozen Sushi dated 02/01/2025 does not indicate that temperature checks at receiving are necessary to control pathogen growth. I observed the document Receiving Log 001 dated 02/20/2025-02/24/2025. It documents the receipt of (b) (4) shipments of (b) (4) (b) (4) received on 02/21/2025, 02/25/2025, and 02/26/2025 which all had a recorded surface temperature of (b) (4)

OBSERVATION 3

Your sanitation control records do not accurately document the conditions or practices observed at your firm.

Specifically,

A. The document Cleaning and Sanitation Program SOP 035 dated 11/18/2024 SOP states on page 6, (b) (4) (b) (4) (b) (4) On 02/26/2025, I observed employees entering the facility at the beginning of production. An employee walked past the handwashing sink without washing their hands and a manager asked them to wash their hands. About (b) (4) of employees I observed washed their hands for less than 20 seconds. The main handwashing sink where employees enter contains (b) (4) faucets with (b) (4)

(b) (4) to operate. One faucet was not functioning at all, another only turned on intermittently while employees were washing hands. The Daily SSOP Inspection – Log 056-A dated 02/26/2025 shows rows titled (b) (4) and (b) (4) (b) (4) These rows both indicate satisfactory conditions.

B. On 02/24/2025, I observed (b) (4) employees walk into the (b) (4) room wearing (b) (4) gloves, touched the door handles, then touched RTE spicy crab sushi without changing gloves or washing hands. On 02/24/2025, I observed an employee touch their face mask, then continued touching RTE spicy crab sushi without changing gloves or washing hands. The Daily SSOP Inspection – Log 056-A dated 02/24/2025 shows rows titled (b) (4) and (b) (4) Both rows indicate satisfactory conditions with the exception of the note, (b) (4)

C. Per the document Cleaning and Sanitation Program SOP 035 dated 11/18/2024 section 6.4, Validation, Monitoring, and Verification of Sanitation Effectiveness, "(b) (4) is performed (b) (4) (b) (4) as per Microbiological Testing Program SOP 040 and recorded on (b) (4) Tests Log 026". The document Microbiological Testing Program – SOP 040 dated 02/06/2023 outlines the procedure for (b) (4) Testing on page 5 which states, (b) (4) (b) (4) (b) (4) It also says, (b) (4) (b) (4) The document (b) (4) Tests Log 026 states a reading of (b) (4) is considered a passing test. On 02/26/2025 I observed the pre-operational inspection conducted by QA personnel. They measured three food-contact surfaces in sushi production areas with (b) (4). The (b) (4) rice (b) (4) part of the sushi rolling machine measured (b) (4) It was re-washed and measured (b) (4). The (b) (4) sushi belt in the (b) (4) room measured (b) (4) The same belt was swabbed in another area and measured (b) (4). The belt was not re-washed between (b) (4) or before production of RTE spicy crab sushi rolls. The (b) (4) sushi belt in the (b) (4) room measured (b) (4) The surface of the belt was sprayed with (b) (4) sanitizer, allowed to dry, and re-tested. The second test measured (b) (4) The belt was then scrubbed with (b) (4) allowed to dry, then measured. The third test measured (b) (4), then the surface was sanitized. On 02/26/2025,

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following observation of the Pre-Op Inspection, I received a copy of (b) (4) Tests Log 026 dated 12/21/2024-02/26/2025 that was still in use. No (b) (4) values from the Pre-Op Inspection that morning were recorded on the Log. The (b) (4) is calibrated (b) (4) and was not calibrated before use on 02/26/2025.

D. On 02/24/2025, I observed a (b) (4) sanitizer stored on top of a (b) (4) in the Prep Cooler. The Daily SSOP Inspection – Log 056-A dated 02/24/2025 shows rows titled "Chemicals are properly labeled" and "Ingredients, WIP, packaging materials, utensils, tools, and finished products are properly labeled, stored, and/or used within time constraints." Both rows indicate satisfactory conditions.

E. On 02/26/2025 during the Pre-Op inspection, I observed visible debris on the surface of thick, reusable (b) (4) gloves used to rinse and prep raw rice. The gloves are not cleaned and sanitized on a regular basis. The Daily SSOP Inspection – Log 056-A dated 02/26/2025 shows a row titled "Inspect equipment, FCS, and utensils for cleanliness". This row indicates satisfactory conditions with the exception of the (b) (4) (b) (4) and (b) (4) belt with reported residue.

F. On 02/26/2025 I observed a (b) (4) used to make sauce with visible (b) (4) chips missing and repair made to the lid with (b) (4) tie. The Daily SSOP Inspection – Log 056-A dated 02/26/2025 shows a row titled "Inspect utensils and containers for cracks or chips" This row indicates satisfactory conditions.

***DATES OF INSPECTION**

2/24/2025(Mon), 2/25/2025(Tue), 2/26/2025(Wed), 2/27/2025(Thu), 2/28/2025(Fri), 3/03/2025(Mon)

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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."