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	5/12/2025-5/21/2025* FEI NUMBER 3015336929

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pedro C. Courard, CEO

FIRM NAME	STREET ADDRESS
ATLANTIC SAPPHIRE USA LLC	22275 Sw 272nd St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Homestead, FL 33031-3758	Salmon Aquaculture Farm and 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

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

Specifically,

A. Your HACCP plan titled, "Head on Gutted and Fillet Packing" QA-HACCP-001 signed and dated 03/04/2025 lists the hazard of Decomposition and does not list the food safety hazard of pathogenic bacteria growth and toxin formation at the (b) (4) CCP.

B. Your HACCP plan titled, "Head on Gutted and Fillet Packing" QA-HACCP-001 signed and dated 03/04/2025 lists the hazard of Decomposition "and may produce biogenic amines (e.g., histamine)" and does not list the food safety hazard of pathogenic bacteria growth and toxin formation at the (b) (4) (b) (4) CCP. In addition, your critical limit states "Maximum (b) (4) temperature of (b) (4)" which is not adequate to control the hazard of pathogenic bacteria growth and toxin formation.

OBSERVATION 2

You did not take corrective action that ensured affected product was not entered into commerce.

Specifically,

On 05/13/2025, you deviated from your critical limit of "Maximum (b) (4) temperature of (b) (4)" at the (b) (4) CCP, as listed on your HACCP plan titled, "Head on Gutted and Fillet Packing" QA-HACCP-001 signed and dated 03/04/2025. On 05/13/2025, your firm processed fresh, raw, whole

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lissette Paiz, Investigator Manuel F Uribe, Investigator	X Lissette Paiz Investigator Signed By: 2001989854 Date Signed: 05-21-2025 15:47:32	5/21/2025

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Pedro C. Courard, CEO	
FIRM NAME ATLANTIC SAPPHIRE USA LLC	STREET ADDRESS 22275 Sw 272nd St
CITY, STATE, ZIP CODE, COUNTRY Homestead, FL 33031-3758	TYPE ESTABLISHMENT INSPECTED Salmon Aquaculture Farm and Processor

salmon and salmon fillets under Purchase Order/ Batch No. (b) (4) and Lot (b) (4). Your firm did not follow your corrective actions of "(b) (4)". Your firm shipped (b) (4) cases of finished product from Batch No (b) (4) to a customer on (b) (4) under Sales Order No. (b) (4).

OBSERVATION 3

Your HACCP plan includes a corrective action plan that is not in accordance with 21 CFR 123.7(b) to ensure the cause of the deviation was corrected.

Specifically, your HACCP plan titled, "Head on Gutted and Fillet Packing" QA-HACCP-001 signed and dated 03/04/2025 lists a corrective action of "If necessary, (b) (4) (b) (4)", at the (b) (4) CCP, which does not ensure that the critical limit of the salmon must not exceed (b) (4) is met. In addition, the cause of the deviation is not addressed.

***DATES OF INSPECTION**

5/12/2025(Mon), 5/13/2025(Tue), 5/21/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lissette Paiz, Investigator Manuel F Uribe, Investigator X Lissette Paiz Investigator Signed By: 2001989854 Date Signed: 05-21-2025 15:47:32	5/21/2025

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."