



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

94835d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

May 25, 2004

WARNING LETTER

NWE-17-04W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joel Frantzman, President and Co-owner
Leslie C. Harlow, Vice President and Co-owner
Sullivan Harbor Farm, Inc.
U.S. Route 1, P.O. Box 96
Sullivan, ME 04664

Dear Mr. Frantzman and Ms. Harlow:

We inspected your seafood processing facility, Sullivan Harbor Farms, located at U.S. Route 1, Box 96, Sullivan, ME on February 24-26, 2004 & March 22, 2004. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of this part, renders the fishery products of that processor adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your ready-to-eat (RTE), cold smoked, vacuum packed Atlantic salmon product ("Salmon Product") is adulterated in that the product has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find this Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The serious deviations observed during the inspection were as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for your

Salmon Product lists a critical limit, of [REDACTED] water-phase salt at the 'Salting' critical control point that is not adequate to control pathogen growth and toxin formation due to time/temperature abuse. FDA recommends that your HACCP plan list maximum time and temperature exposure of the product during the salting process, and include monitoring of these parameters to control the hazards of pathogen growth and toxin formation.

In addition, your HACCP plan for your Salmon Product does not list the monitoring frequency of water-phase salt at the 'Salting' critical control point to control pathogen growth and toxin formation. For example, your firm has set a critical limit for water-phase salt at [REDACTED] but has not specified the frequency for monitoring this critical limit. Under your current HACCP Plan, testing for water-phase salt (WPS) should occur for each lot. Testing each lot will ensure that the corrective actions stated in your HACCP Plan for the 'Salting' critical control point are effective.

We acknowledge your response letter dated 3/23/04 wherein you indicated that you will perform WPS tests every three months. This is still not adequate to monitor your specified critical limit.

As you may know, you may choose to revise your critical limit at your 'Salting' critical control point to reflect your product recipe. In addition to identifying maximum time and temperature parameters during the 'Salting' critical control point, you may wish to include thickness of fish, and ratio of salt to fish to achieve consistent salt concentration in your finished product. This may be an effective way to monitor water-phase salt in your finished product to control the hazard of pathogen growth and toxin formation. Under such circumstances, a verification step of testing WPS every three months may be adequate.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6 (a) and (c) (2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for your Salmon Product does not list the critical control point(s) of 'Receiving' and 'Receiving Cooler' for controlling the food safety hazard(s) of pathogen growth.

Because pathogens can survive the cold smoking process, your firm needs to assure that products are maintained below 40°F during raw material transportation and storage. Monitoring the adequacy of ice, instead of continuous temperature recording, is acceptable. However, if you choose to

Sullivan Harbor Farm, Inc.
Sullivan, ME 04664
Page 3

monitor the adequacy of ice, FDA recommends monitoring at least twice per day during refrigerated storage.

We may take further action if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response any documentation, such as your revised HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Current Good Manufacturing Practice (cGMP) regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail F. Costello
District Director
New England District Office