



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94446d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 10, 2003

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-11

Horst A. Schramm, President
Horst's Seafood Co., Inc.
2315 Industrial Boulevard
Juneau, Alaska 99801

WARNING LETTER

Dear Mr. Schramm:

On August 13 and 15, 2003, we inspected your seafood processing facility, located at 2315 Industrial Boulevard, Juneau, Alaska. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, 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 otherwise operate in accordance with the requirements of this part, renders the fishery products 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 refrigerated vacuum packaged smoked salmon products are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health. You may find the Act, the Seafood HACCP regulation, and the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, through links in FDA's homepage at www.fda.gov.

The deviations are as follows:

- 1) You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures at the "freezing" critical control point to control parasites as listed in your HACCP plan for cold smoked salmon. Your plan provides that each day a [REDACTED] " You have not conducted a visual check on a daily basis. Moreover, you must maintain records documenting appropriate monitoring to comply with 21 CFR 123.6(b)(7), however, you have not kept a record of the monitoring.

- 2) You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plans for vacuum packaged Hot and Cold Smoked Salmon list a monitoring procedure at the brining critical control point that is not adequate to control Clostridium botulinum. Monitoring should directly measure the factors for which you have established a critical limit, and critical limits must be monitored often enough so that normal variability in the values you are measuring will be detected. Your HACCP plans list monitoring of brine recipe and brine time to directly measure the critical limit of water phase salt (WPS). These procedures are not adequate as they do not directly measure the critical limit of WPS.

Moreover, your firm's HACCP plans for Hot and Cold Smoked Salmon list monitoring procedures/frequencies at the refrigerated storage critical control point that are not adequate to control pathogens because they fail to provide for continuous monitoring. FDA recommends that the temperature of your cooler for your ready to eat salmon products be monitored continuously together with a daily visual check.

In addition, your monitoring procedure/frequency at the smoking/cooking critical control point in your HACCP plan for Hot Smoked Salmon is inadequate. You monitor the internal temperature of only one fish. FDA recommends you monitor the internal temperature of the thickest part of three of the largest fish in the smoking chamber.

- 3) You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limit of WPS for Hot Smoked Salmon at the brining critical control point (CCP) to control Clostridium botulinum growth and toxin production. In fact, the test data you produced at the inspection as evidence of verification showed that critical limit was not met. In addition, FDA collected a sample of hot smoked salmon, FDA Sample Number 240718, and found that water phase salt levels for all ten subsamples of this product ranged from 1.9% to 3.0%. Since these water phase salt percentages are well below FDA safety recommendations and your critical limit, your process appears to be inadequate. Consequently, FDA has determined that any verification measures taken by your firm, with regard to your process, had been inadequate.
- 4) Since you chose to include corrective actions in your HACCP plans, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for Hot and Cold Smoked Salmon at the brining critical control point is not appropriate in that the plans do not address correcting the cause of the deviation. It simply provides: "[h]old for evaluation and take appropriate action."

Horst A. Schramm, President
Horst's Seafood Co., Inc., Juneau, Alaska
Re: Warning Letter SEA 04-11
Page 3

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

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response 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 you will explain the reason for your delay and state when you will correct any remaining deviations.

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 regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

cc: ADEC with disclosure statement