



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Telephone: 425-486-8788
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May 7, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-27
Marko A. Petrich, President
Tony's Smokehouse & Cannery, Inc.
1316 Washington Street
Oregon City, Oregon 97045-1649

WARNING LETTER

Dear Mr. Petrich:

On December 16, 17, 18, and 19, 2003, we inspected your seafood processing facility, located at 1316 Washington Street, Oregon City, Oregon. 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 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 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 fully document, in records, all corrective actions taken, to comply with 21 CFR 123.7(d). However, your firm did not document that a corrective action was taken when you deviated from the critical limits listed in your HACCP plan for refrigerated vacuum packaged smoked salmon products at the "Smoking/Cooking" critical control point.
 - a) Specifically, the critical limit at the "Smoking/Cooking" critical control point as listed in your plan is to obtain a minimum temperature in fish of [REDACTED] F for [REDACTED] minutes. However, on the following occasions you did not meet this critical limit.
 - Two batches of hot smoked salmon, Lot #304, were produced on October 31, 2003. The temperature reached a high of [REDACTED] F for [REDACTED] minutes for one batch, and

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the temperature reached a high of between [REDACTED]°F and [REDACTED]°F for [REDACTED] minutes for the other batch.

- One batch of hot smoked salmon, Lot #308, produced on November 4, 2003, reached a high of between [REDACTED]°F and [REDACTED]°F.
- One batch of hot smoked salmon, Lot #337, produced on December 3, 2003, reached a high of [REDACTED]°F to [REDACTED]°F for [REDACTED] minutes.

You were unable to provide any documentation demonstrating whether an appropriate corrective action was taken or what the final disposition was for these lots of product. Your HACCP plan lists that if internal temperature of [REDACTED] degrees for [REDACTED] minutes is not reached you will recook, and if a second cook does not reach the required time and temperature, you will destroy the product. Your plan also lists that you will fill out a corrective action sheet. However, there is no evidence or corrective action sheet to indicate that these lots of product were recooked or destroyed.

- 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 plan for refrigerated vacuum packaged smoked salmon does not list adequate monitoring procedures at the "Cooling/Post Smoke" critical control point. For example, you do not list whether you are monitoring the ambient temperature of the cooler or internal temperature of the fish. In addition, you do not describe how you are performing this monitoring (i.e. type of equipment used).
- 3) Because you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for refrigerated vacuum packaged smoked salmon at the "Brining & salt content" and "Storage and distribution" critical control points are not appropriate. The corrective actions do not address holding and evaluating product to assure that unsafe product does not reach the consumer.

In addition, the corrective action plans for your refrigerated vacuum packaged smoked salmon as listed in your HACCP plan at the "Smoking/Cooking" and "Cooling/Post Smoke" critical control points are not appropriate. Your written corrective actions do not include addressing correction of the cause of the deviation from the critical limits.

For your information, FDA notes that 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.

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.

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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 Current 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,

Celeste M. Corcoran

for

Charles M. Breen
District Director

cc: OSDA with disclosure statement