



DEPARTMENT OF HEALTH & HUMAN SERVICES

MSZ19A

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

March 1, 2001

Our Reference: 2954143

Auggie Wilms, Owner
Ohlone Smoke Company
1607 - 63rd Street
Emeryville, California 94608

WARNING LETTER

Dear Mr. Wilms:

We inspected your seafood processing facility on September 21 and 25, 2000. We conducted this inspection to determine your compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. The deviations cause your refrigerated, ready-to-eat, vacuum packaged smoked salmon to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that the fish have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. We discussed these deviations with you at the conclusion of the inspection. Your serious HACCP deviations are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for hot smoked fish does not list adequate critical limits at the brining critical control point (CCP) to control *Clostridium botulinum* toxin formation as evidenced by the low levels of water phase salt found in the sample of hot smoked salmon collected and analyzed by FDA during the current inspection of your firm. The FDA laboratory found that five of ten sub-samples have water phase salt below 3.5 percent. To control *C. botulinum* toxin formation in a vacuum packaged smoked fish or smoke-flavored fish, the guideline for water phase salt is 3.5 percent or higher. Water phase salt below 3.5 percent would not provide a preventive control for *C. botulinum* toxin formation in a refrigerated, vacuum packaged, smoked fish or smoke-flavored fish product. Additionally, we found that your HACCP plan for the cold smoked and hot smoked fish lists a 50°F critical limit at the cooler storage CCP that is not adequate to control *C. botulinum* toxin formation. Refrigeration would need to be strictly controlled at 38°F to prevent the growth of *C. botulinum* type E and nonproteolytic type B and F. Pathogens other than *C. botulinum* that may be introduced during the process could also grow to unsafe levels if the smoked fish is allowed to remain at temperatures above 40°F.

2. You must implement the monitoring procedures and frequency listed in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring frequency of visual observation of the smoker temperature twice during the cold smoking process, to control *C. botulinum* toxin formation, as listed in your HACCP plan for cold smoked fish. This deviation is evidenced by your Cold Smoking Temperature Records from August 17 to September 4, listing only one smoker temperature for each day of manufacture. Investigator Bracy also observed during the inspection that only one of your smokers was equipped with a thermometer. Additionally, during the hot smoking operations, your firm did not monitor the salinity of the brine solution before use, and you did not monitor the internal temperature of the fish continuously at the smoke/cooking CCP.

3. You must take an appropriate corrective action whenever a verification procedure indicates a need, in order to comply with 21 CFR 123.8(b). However, your firm did not take appropriate corrective action to control *C. botulinum* toxin formation when your verification procedure of private laboratory testing indicated that the water phase salt in a lot of hot smoked salmon was below the desired 3.5% level.

4. You must adequately monitor and document sanitation conditions and practices, in order to comply with 21 CFR 123.11(b) and (c). However, your firm did not monitor and maintain records related to the prevention of cross-contamination from insanitary objects; the protection of food, food packaging material, and food contact surfaces from adulteration with condensate and other chemical, physical, and biological contaminants; the proper labeling, storage, and use of toxic compounds; the control of employee health conditions that could result in microbiological contamination; and the exclusion of pest from your facility, with sufficient frequency to ensure sanitation control during processing. Examples of insanitary conditions and poor employee practices include the following:

- a) Employees failed to wash and sanitize their hands prior to putting on gloves and handling ready-to-eat seafood;
- b) Employees touched unsanitary surfaces (cooler doors, towels used to wipe dirty food surfaces) and began handling ready-to-eat seafood without first washing or sanitizing their hands;
- c) Condensate from a cooling fan directly above an uncovered bin containing salmon in brine;
- d) Dirty condenser blowing air directly on ready-to-eat trout.

Sufficient time has passed for you, since our inspection of September 2000 and our presentation of the FDA-483 Inspectional Observations to you, to correct the violations at your facility. If you have not made such corrections, you must immediately take appropriate steps to correct the violations. We may initiate regulatory action without further notice if you do not correct these problems. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

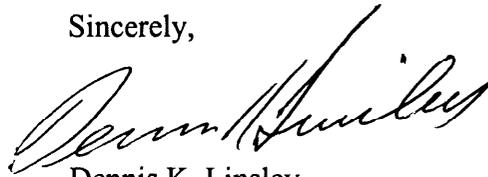
Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented or will implement to correct these deviations, including an explanation of each

step being taken to prevent their recurrence. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation 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 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. 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: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is fluid and cursive, written over a white background.

Dennis K. Linsley
Director
San Francisco District