



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
New England District

94539d

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**WARNING LETTER**  
**NWE-19-04W**

**VIA FEDERAL EXPRESS**

February 4, 2004

Carl R. Johnson, Owner  
Roger F. Billings, Owner  
Grindstone Neck of Maine, LLC  
311 Newman Street  
Winter Harbor, ME 04693

Dear Mr. Johnson and Mr. Billings:

We inspected your seafood processing facility, Grindstone Neck of Maine, LLC, located at 311 Newman St., Winter Harbor, ME, on October 29-31 and November 3, 2003. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (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 processed there 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 RTE cold smoked vacuum packed Atlantic and Wild Sockeye salmon products are adulterated in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find this Act, the seafood HACCP regulation, and FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The serious deviations observed during the inspection were as follows:

1. 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 food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c) (1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's

HACCP plan for RTE cold smoked vacuum packed Atlantic and Wild Sockeye salmon products does not list the food safety hazard of parasites. Wild Ocean caught salmon and aquaculture raised salmon that have been fed mixtures containing fresh fish or plankton may contain parasites in their flesh and consequently pose a health hazard when consumed uncooked, undercooked or unfrozen. The cooking temperatures used in cold smoking will not likely reduce or eliminate parasites in the final products for these type salmon. We suggest that you refer to Chapter 5: Parasites in the FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition for additional information and recommended preventative measures.

2. 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." Although you consider "weight loss" a critical limit for the curing CCP, it is not listed as a critical limit in your plan. Your plan merely lists "weight loss" in the column for "what" will be monitored. Your plan does not provide the critical limit value (i.e., total drip loss in pounds, ounces, etc.) associated with this weight loss.
3. 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 RTE cold smoked vacuum packed Atlantic and Wild Sockeye salmon products does not list adequate monitoring procedures at the curing critical control point to control the listed critical limits. The critical limits in your plan indicate that you are controlling salting at a ratio of [REDACTED] (i.e., of fish) and process time at [REDACTED] (i.e., of fish) thickness. Your procedures for "how" monitoring is to be performed list a "visual note of color/turgidity." This visual check of color/turgidity is not adequate for monitoring and controlling the salting ratio and the process time.
4. You must implement the record keeping system that you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at several critical control points listed in your HACCP plan.
  - Your firm did not record monitoring observations at the cooling critical control point to control pathogen growth hazard listed in your HACCP plan for RTE cold smoked vacuum packed Atlantic and Wild Sockeye salmon products. You are not maintaining records to demonstrate that cooling is monitored on [REDACTED] basis as listed in your HACCP plan at the cooling critical control point.

- Your firm has not implemented the record keeping system listed in your HACCP plan at the curing critical control point.
5. Since you chose to include corrective actions in your HACCP plan, your described corrective action procedures must be appropriate to comply with 21 CFR 123.7(b). A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and the cause of the deviation is corrected. However, your corrective action plan for your RTE cold smoked vacuum packed Atlantic and Wild Sockeye salmon products at the smoking critical control point to control *Clostridium botulinum*, and at the cooling and storage critical control points to control pathogen growth is not appropriate because it does not take steps to ensure that the cause(s) of the deviations are corrected--it simply provides reheating instructions. Please see FDA's Fish and Fishery Products Hazards and Controls Guidance: Third Edition for several examples of corrective action procedures that FDA recommends.

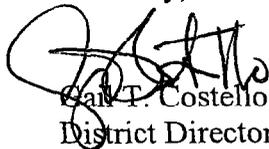
We may take further action if you do not promptly correct the above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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 the deviations. You should include in your response any documentation, such as your revised HACCP plan, copies of completed monitoring records, 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 regulation (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.

You may direct your reply to Ann Simoneau, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Simoneau at (781) 596-7732.

Sincerely,



Paul T. Costello  
District Director

New England District Office