



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94891d

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WARNING LETTER
NWE-32-04W

Certified Mail
Return Receipt Requested

July 16, 2004

Richard Howe, President
Stonington Sea Products, Inc.
100 North Main Street
Stonington, ME 04681

Dear Mr. Howe:

We inspected your seafood processing facility, Stonington Sea Products, Inc., located at 100 North Main Street, Stonington ME, on April 6-7, and 13, 2004. As part of the inspection, finished product samples of your ready-to-eat (RTE) cold-smoked, vacuum-packed Atlantic salmon were collected and analyzed for *Listeria monocytogenes*. FDA confirmed the presence of *Listeria monocytogenes* in a lot of your product which causes the lot of seafood to be adulterated within the meaning of Section 402(a)(1) of the Federal, Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(1), in that the product bears or contains a poisonous or deleterious substance which may render it injurious to health.

We also 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 adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4). Accordingly, your RTE cold-smoked, vacuum-packed Atlantic salmon products are adulterated in that the products 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 can find this Act, the seafood HACCP regulation, and FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition ("Fish Products Guidance") through links in FDA's home page at www.fda.gov.

The serious seafood HACCP 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 "Cold Smoked Salmon" does not list the food safety hazard of parasites. Wild ocean-caught salmon, or farm-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 Products Guidance for additional information and recommended preventative measures.
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 "Cold Smoked Salmon" does not list the processing step of salmon receiving as a critical control point for controlling the food safety hazards of pathogen growth and toxin formation. Because pathogens can survive the cold smoking process, FDA recommends that your firm take steps to ensure that raw fish is maintained below 40°F during transportation. You may refer to FDA's Fish Products Guidance for additional information and recommended preventative measures.
3. 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 "Cold Smoked Salmon" lists a critical limit, "[REDACTED] at the "Dry Cure" critical control point that is not adequate to control the hazard of pathogen growth and toxin formation due to time/temperature abuse. FDA recommends that your dry salting process be maintained at 40°F or below, and that your HACCP plan list the maximum time and temperature exposure of the product during the salting process to control the hazards of pathogen growth and toxin formation.

In addition, FDA recommends that the dry salting start and stop times be documented and that the air temperature be monitored with a continuous temperature recording device. FDA notes that when changing your dry salting critical limits you will need to revalidate the process, which may include testing final product water phase salt.

4. 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:

a. Your firm's HACCP plan for "Cold Smoked Salmon" lists a monitoring frequency at the Cooler Storage critical control points that is not adequate to control pathogen growth and toxin formation during raw material, in-process and finished product storage. [REDACTED] does not provide sufficient temperature control during cooler storage. FDA recommends monitoring a cooler temperature (critical limit = 40°F) with a continuous temperature recording device. Monitoring the adequacy of ice, such as during your raw material storage, is another acceptable method of continuous temperature monitoring. However, if you choose to monitor the adequacy of ice during refrigerated storage, FDA recommends monitoring at least twice per day.

b. Your firm's HACCP plan for "Cold Smoked Salmon" lists a monitoring procedure at the "Cold smoke" critical control point that is not adequate to control pathogen growth and toxin formation. Your plan indicates that [REDACTED] and also lists a monitoring procedure [REDACTED]

[REDACTED] However, FDA recommends the use of a monitoring procedure that directly measures the critical limit temperature for the cold smoke critical control point (i.e. digital time/temperature data logger, recorder thermometer, maximum indicating thermometer, or high temperature alarm). During the inspection, our investigators observed that your firm uses a [REDACTED]

[REDACTED] Moreover, during the inspection, our investigator observed that the [REDACTED] when the [REDACTED] Chapter 13 of FDA's Fish Products Guidance contains examples of recommended monitoring procedures during cold smoking.

5. 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 plan for "Cold Smoked Salmon" at the "Dry Cure" critical control point to control pathogen growth is not appropriate. The corrective action plan does not [REDACTED]

[REDACTED] In addition, your firm has [REDACTED]
[REDACTED] FDA recommends testing water phase salt at least quarterly.

6. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor sanitation conditions adequately and with sufficient frequency to ensure control, as evidenced by observed deficiencies from the Current Good Manufacturing Practices (CGMP) regulation (21 CFR Part 110) listed below:
 - raw salmon fillets were placed on cooking racks which contained food residues and exposed to ambient room temperatures [21 CFR 123.11(b)(3)];
 - rust from racks used to hold clean totes behind the fish cutting tables were observed to be falling into the totes [21 CFR 123.11(b)(5)];
 - totes containing brined cod were taken from storage on the floor of the cooler, placed on a sanitized stainless steel work bench and immediately thereafter, fish product was removed and packaged on that same work bench [21 CFR 123.11(b)(3)]; and
 - employees were observed to have direct contact with exterior surfaces of product shipping cartons, then to the salmon fillets without washing their hands [21 CFR 123.11(b)(3)].

We may take further action if you do not promptly correct the above 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 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.

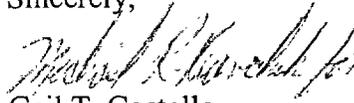
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures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

Stonington Sea Products, Inc.
Stonington, ME
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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,



Gail T. Costello
District Director
New England District Office