



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94729d

Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

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May 19, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-29

Scott M. Kimmel, President
New Day Fisheries, Inc.
2427 Washington Street
Port Townsend, Washington 98368

WARNING LETTER

Dear Mr. Kimmel:

On February 12 and 13, 2004, we inspected your seafood processing facility, located at 2427 Washington Street, Port Townsend, Washington. 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) and the Low Acid Canned Food (LACF) regulation (21 CFR 113).

In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with 21 CFR 123, 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)). Further, based upon certain criteria in Part 113, low acid canned food may be adulterated within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(3)) in that it consists in whole or in part of any filthy, putrid, or decomposed substance or if it is otherwise unfit for food, or within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)) in that it may have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. Further, it is a prohibited act, under section 301(k) of the Act (21 U.S.C. 331(k)), to adulterate a food while the food is held for sale after shipment in interstate commerce.

Accordingly, your seafood products are adulterated in that they may have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, the LACF regulation, and the Fish & Fisheries Products Hazards & Controls Guidance: Third Edition, June 2001, through links in FDA's homepage at www.fda.gov.

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The deviations are 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 Pickled Herring does not list the food safety hazards of parasites and *Clostridium botulinum*.
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 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 Cooked and Peeled Shrimp Meat does not list the critical control point of cooler storage to control the food safety hazard of pathogen growth. We also recommend that you establish a critical control point to monitor the cooling, peeling, and packing time. Your cooked shrimp should be cooled to below 70°F within 2 hours and below 40°F within the subsequent 2 hours if the shrimp are significantly handled (peeled) prior to full cooling (below 40°F).

Additionally, your firm's HACCP plan for Pickled Herring does not list the critical control point of Pickling. According to our latest inspection, your herring products are placed in pickling solution and held for up to a week. The temperatures of either the pickling solution or the cooler should be monitored continuously during that time period.

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, the following HACCP plans list critical limits that are not adequate to control the identified food safety hazard:

Your firm's HACCP plan for Albacore Tuna lists a critical limit at the Receiving critical control point that is not adequate to control histamine formation. Specifically, you are not evaluating your incoming product for decomposition at receipt. Additionally, your harvest vessel certificates do not provide the safety assurances that are equivalent to harvest vessel records. For more information on sensory examination of scombroid species and harvest vessel records you may wish to

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review Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance: Third Edition.

Your HACCP plan for Albacore Tuna also lists a critical limit at the Thawing, Hand Filleting, & Packing Jars critical control point that is not adequate to control scombrototoxin formation. FDA recommends monitoring ambient temperatures, rather than internal temperatures, since internal temperatures are frequently lower than surface temperatures and vary from piece to piece.

Your HACCP plan for Pickled Herring lists a critical limit at the Receiving critical control point that is not adequate to control histamines. Since you receive fresh herring that is transported in excess of 4 hours, internal temperature checks at receipt is not considered an adequate control of histamines. FDA recommends monitoring the presence of cooling media at receipt or requiring some method of continuous time/temperature monitoring during transportation.

Your HACCP plan for Cooked Dungeness Crabs lists a critical limit "Cool to 40 degrees or below within ■ hours" at the Cooling critical control point that is not adequate to control pathogen growth. FDA considers the cool down from 140°F to 70°F within 2 hours a critical period and you should assure rapid cooling during that time period. If you can show that your crabs have cooled to below 40°F within two hours we support establishing that as your critical limit. However, if you are unable to cool your crabs to 40°F in that time period, you should list the two-step cool down criteria (below 70°F within 2 hours and below 40°F within the subsequent 4 hours).

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, your firm's HACCP plans for Albacore Tuna and Pickled Herring lists monitoring procedures at the "Storage Temperature" critical control point (CCP) that are not adequate to control the significant hazard of scombrototoxin formation. Your firm's HACCP plans list a monitoring procedure of visually checking the thermometer in the cooler ■ times per day. This is an inadequate frequency for detection of variations in the temperature. Monitoring must be continuous with an instrument such as a time/temperature data logger combined with a visual check of the instrument at least once per day. You were advised of this during two previous inspections yet the monitoring procedure remains unchanged.

Your firm's HACCP plan for Albacore Tuna also lists an inadequate monitoring frequency at the Thawing, Hand Filleting, and Packing Jars critical control point that is not adequate to control scombrototoxin formation. Your plan lists a monitoring frequency of "each batch thawed" although your critical limit states that you will not let the fish reach temperatures above 40°F for more than ■ hours. You should list a monitoring frequency that is often enough to assure that your critical limit is not exceeded.

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In addition, your firm's HACCP plan for Dungeness Crabs lists a monitoring procedure at the Cooking critical control point that is not adequate to control the hazard of pathogen survival. Your monitoring procedure should be more specific regarding the sampling criteria. You should be selecting and testing the largest crab(s) in the batch from the coldest spot. The number of crabs tested per batch and the basis for selection should be included in the plan.

5. Since 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 Dungeness Crabs at the Cooling and Storage critical control points to control the hazard of pathogen growth are not appropriate. Your corrective actions at the Cooling and Storage critical control points do not assure that unsafe product will not enter commerce. You should also evaluate the exposure times and temperatures and reject the product if the abuse was sufficient to make the product potentially unsafe.
6. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for safety of water that comes into contact with food or food contact surfaces.

LACF Deviations:

7. You must properly vent and reach the processing temperature prior to timing the process, to comply with 21 CFR 113.40(a)(12). However, on October 18, 2003, when processing your albacore in olive oil and albacore in water products, you failed to properly vent prior to timing the process. According to a letter from your process authority dated December 21, 1998, "The vent shall remain wide open for at least [REDACTED] minutes after steam is admitted to the retort, and until the mercury-in-glass thermometer indicates at least [REDACTED]°F."
8. You must fully reprocess or set aside for evaluation of public health significance any product that receives a process less than the scheduled process, to comply with 21 CFR 113.89. You did not identify a process deviation and, as a result, improperly processed product was distributed. On October 18, 2003, raw albacore tuna packed in 8 oz. glass jars did not receive a thermal process as recommended by your processing authority. The vent was for [REDACTED] minutes instead of the required [REDACTED] minutes. During the previous inspection FDA also identified a process deviation that you had not identified. Although in each case you have subsequently obtained an evaluation from your processing authority that the distributed products were commercially sterile, you have failed to implement adequate procedures to assure records are sufficiently reviewed and process deviations are evaluated prior to product distribution.

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9. A representative of the plant management who is qualified by suitable training or experience must review all processing and production records for completeness and to assure that the product received the scheduled process, to comply with 21 CFR 113.100(b). However, on October 18, 2003, your reviewer signed and dated the Daily Retort Process Records as being complete even though the product had not received your scheduled process. Specifically, your vent was for ■ minutes instead of the required ■ minutes.
10. Production records must be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific lots of food if that food has become contaminated or is otherwise rendered unfit for the intended use, to comply with 21 CFR 113.100(d). You were unable to identify the consignees of the raw albacore tuna that was vented at a time less than that required in the scheduled process.

We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) 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 assuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the LACF regulation. 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,



Charles M. Breen
District Director

cc: WSDA with disclosure statement