



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
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Minneapolis, MN 55401
Telephone: (612) 334-4100
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September 23, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 35

Charles W. Henriksen
President/Owner
Henriksen Fisheries, Inc.
1597 Birch Road
Bailey's Harbor, Wisconsin 54202

Dear Mr. Henriksen:

On June 5 and 9, 2003, we inspected your seafood processing facility, located at 10570 Old Stage Road, Sister Bay, Wisconsin. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, 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 chub roe/caviar is adulterated, in that the chub roe/caviar has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or it may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links on FDA's home page at www.fda.gov.

The deviations on the issued form FDA-483, Inspectional Observations, of most concern are as follows:

- 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 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 chub roe/caviar does not list critical limits at "receiving,"

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and thus does not include steps that are adequate to control pathogen growth and toxin formation in this product.

We note that you have listed a critical limit of "40°F" at the "receiving" process step. FDA recommends that you identify receiving as a critical control point for products such as your raw seafood, *e.g.*, chub roe, that will be consumed without any subsequent heat treatment, and that the critical limit be "40°F or less throughout distribution." To ensure that the product temperature does not exceed 40°F, FDA recommends monitoring the adequacy of ice or chemical cooling medium at the time of delivery. Alternatively, you may wish to maintain monitoring records of the internal temperature of the fishery product or the temperature of the truck or other carrier throughout transportation. If transit time is less than four hours, FDA believes that it is acceptable to establish that the warmest temperature in the lot of product at receipt is 40°F or less. More specific guidance on acceptable critical limits can be found in Chapters 12 and 13 of the *Fish & Fisheries Products Hazards & Controls Guidance: Third Edition*. This publication is available at our website listed above.

- 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 chub roe lists monitoring procedures at the "Receiving" and "Salting Stage" critical control points that are not adequate to control pathogen growth and toxin formation. Your HACCP plan lists the monitoring procedures of "Batch Number" and "Salting Log" for the "Receiving" and "Salting Stage" critical control points, respectively. FDA recommends that the listed monitoring procedures list what, how, who, and the frequency of monitoring. More guidance regarding acceptable monitoring procedures can be found in Chapters 12 and 13 of the *Fish & Fisheries Products Hazards & Controls Guidance: Third Edition*. This publication is available at our website listed above.
- You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the incoming temperature monitoring procedure listed in your HACCP plan for chub roe/caviar for every shipment of roe received to control pathogen growth and toxin formation. Roe temperature was not recorded on the following dates: February 1, 6, 21, 2003, from [REDACTED], November 27, 2002, from source 185; November 26, 2002, January 22, 2003, and February 1, 2003, from source 381.
- 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 chub roe/caviar lists a

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corrective action, "Batch Number" at the "Receiving" critical control point and "Daily log review, rinse & resalt" at the "Salting Stage" critical control points that do not meet the requirements of 21 CFR 123.7(b)(1) and (2) to ensure that no adulterated product enters commerce and the cause of the deviation is corrected.

- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for the processing of chub roe/caviar from 3/21 to 4/3/03.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/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 should 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 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 Compliance Director David R. Yost at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Mr. Yost at (612) 758-7112.

Sincerely,



W. Charles Becoat
Director
Minneapolis District