



DEPARTMENT OF HEALTH & HUMAN SERVICES

94174d
Food and Drug Administration

May 21, 2003

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-15-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Mary E. Parrish, Owner
Fort Massac Fish Market
1117 East 2nd Street
Metropolis, IL 62960

Dear Ms. Parrish:

On January 15, 21, and 23, 2003, we inspected your seafood processing facility, located in Metropolis, Illinois. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulations set forth in 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 refrigerated, ready-to-eat, paddlefish/spoonbill caviar and hackleback sturgeon caviar is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001, through links in FDA's home page at <http://www.fda.gov>.

The deviations were 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 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 "fish eggs (spoonbill & hackleback)":
 - Lists a critical limit, "to make sure you put enough salt to where it will not be too salty or too watery," at the salting process critical control point that is not adequate to control the *Clostridium botulinum* growth and toxin formation hazard that is identified in your HACCP plan.

- Fails to list a critical limit to control the hazards of pathogen growth and toxin formation, including *Clostridium botulinum* in the sealed plastic tubs you receive, at the receiving critical control point. The refrigerated roe you receive is considered ready-to-eat since it is not intended to be further cooked, and the salting process is minimal. Therefore, you should have controls in place to assure that the roe has been safely stored and handled prior to your receipt of the products. This is done by assuring that the roe has been adequately iced or chilled during transport to your firm. You may choose to take internal temperatures if transport times are less than 4 hours or you may ascertain that the shipping ice completely surrounds the containers of roe or take corrective action when it does not.
- 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 monitoring procedures identified in your HACCP plan for “fish eggs (spoonbill and hackleback).” Your plan specifies that you will monitor cooler temperatures with a “continuous recording automatic thermometer.” However, your firm has failed to install this device. FDA does not consider intermittent temperature checks an adequate safety procedure to ensure that safe temperatures are continuously maintained during storage periods.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor two of the eight areas of sanitation with sufficient frequency to ensure control as evidenced by:
 - › Improper labeling, storage, and use of toxic compounds – Containers holding food-contact surface and floor surface sanitizers were stored on the processing room floor and not in a secured cabinet or other segregated area.
 - › Failure to exclude pests from the food plant - there was a cockroach egg case just outside the storage room.

We brought these sanitation issues to your attention during our February 28, March 7 and 8, 2002 inspection of your firm, and noted them on the Form FDA-483 that was issued to you at the conclusion of that inspection.

The above is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed), which is a list of our investigator's observations of deviations noted during the inspection. It is your responsibility to assure that all of your fishery products are processed in compliance with the requirements of the Act, the seafood HACCP regulations (21 CFR Part 123), and the Good Manufacturing Practice regulations (21 CFR Part 110), as appropriate.

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You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to correct these violations, including an explanation of steps that will be taken to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your written reply should be sent to Patrick J. Brown, Compliance Officer, at the address listed in the letterhead.

If you have questions regarding the implementation of the seafood HACCP regulations, you may contact Darrell Luedtke, the Chicago District Seafood HACCP coordinator, telephone (847) 249-8632, for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director