



**CERTIFIED MAIL**  
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Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260

**WARNING LETTER**  
**2003-DT-02**

October 29, 2002

Mr. Bruce G. Osterhaven, Treasurer  
Superior Seafoods, Inc.  
4243 Broadmoor  
Kentwood, MI 49512

Dear Mr. Osterhaven,

On March 4<sup>th</sup> through 7<sup>th</sup>, 2002, the Food and Drug Administration (FDA) conducted an inspection of your firm, Osterhaven, Inc., dba Big O' Fish House, located at 9740 Cherry Valley Road, Caledonia, MI 49316. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123).

During the inspection the FDA investigators observed shortcomings in your system that are deviations from the principles of HACCP and the requirements of 21 CFR 123. 21 CFR 123.6(g) states that failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with its requirements shall render the fishery products of that processor adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your vacuum packaged hot smoked whitefish fillets and your air packaged smoked chubs are adulterated within the meaning of 402(a)(4) in that they have been prepared, packed or held under insanitary conditions whereby they may have been rendered injurious to health. You can find this Act and the seafood HACCP regulations through links in FDA's homepage at <http://www.fda.gov>.

Your deviations are as follows:

1. You must, at a minimum, implement a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your HACCP plan for vacuum packaged smoked whitefish and air packaged chubs list critical limits at the cooling and storage critical control point that are not adequate to control pathogen growth and formation of *C. botulinum* toxin, as evidenced by the following:

- a. Your firm lists "[REDACTED]" as the critical limit at the cooling and storage critical control point for vacuum packed hot smoked fish. The term "within 4 hours" is inadequate because it does not account for accelerated pathogen growth at temperatures above 70°F. The FDA recommends that the temperature of cooked ready-to-eat products be reduced to 70°F or below within 2 hours. The FDA further recommends that once the cooling product is cooled to below 70°F, the process of cooling down to 50°F or below should take no more than 4 hours.
- b. The firm's critical limit at the cooler and storage critical control point for air packed hot smoked fish is "[REDACTED]". This critical limit is inadequate because it does not require that the cooling product be chilled to below 70°F within an acceptable time limit. Since the cooling time/ temperature critical limits required for vacuum packed hot smoked fish are no different than the requirements for air packed product, the firm need only have one cooling time temperature critical limit for hot smoked fish.
- c. In addition, your firm's cooling and refrigerated storage critical control point does not list a temperature critical limit for finished product storage. In order to facilitate the control of pathogen growth and the formation of *C. botulinum* toxin, the FDA recommends 40°F as an acceptable critical limit for refrigerated storage of hot smoked ready-to-eat fish. The 40°F storage temperature is adequate for both air packed and vacuum packed hot smoked fish.

Since the critical limits are different for cooling and storage, you may wish to clarify your HACCP plan by making cooling and storage separate critical control points.

2. You must, at a minimum, implement the record keeping system listed in your HACCP for vacuum packaged hot smoked whitefish, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the brining CCP to control pathogen growth and *C. botulinum* toxin formation, as evidenced by the following:
    - a. Your plan lists a critical limit (CL) of [REDACTED] degrees salimeter or higher at the brining CCP; however you do not record the salimeter readings.
    - b. Your HACCP plan lists a [REDACTED], yet weight of the fish and the weight of the water are not recorded.
    - c. Your HACCP plan lists a (CL) of "minimum [REDACTED] hours brining time for previously frozen product and [REDACTED] hours for fresh products";
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however, based on your records, you do not consistently document the start and end time of your brining.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must, at a minimum, be appropriate, to comply with 21 CFR 123.7 (b). However, your firm's corrective action plan for hot smoked fish at the brining critical control point to control pathogen growth and *C. botulinum* toxin is not appropriate. This is evidenced by the fact that although your HACCP plan cites a critical limit of 15 as a minimum salimeter reading, your corrective actions require that salt be added to the brine if the salimeter reading is less than 25.
  4. During the inspection we also observed sanitation deviations that cause your products to be adulterated within the meaning of 402(a)(4) in that they 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 must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor:
    - a. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces including utensils, gloves, and outer garments, and from raw food to cooked food. The investigators witnessed the bulk packing of air packaged hot smoked chubs into a fiberboard box and saw the employee add a stack of loose retail labels to the contents with no barrier between the product and the labels.
    - b. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product. The investigator noted the firm was using a cracked and chipped paddle to mix water and brine ingredients. In addition, the investigators cited the firm for using plastic cutting boards that were both worn and had deep cuts in the cutting surface. The investigator also noted that the cutting boards were discolored and contaminated with dark colored material caked into the deep cuts on the work surfaces of the boards.
    - c. Proper labeling, storage and use of toxic compounds with sufficient frequency to ensure control. The investigators noted that the firm was using a chemical sanitizer that was not approved for food contact surfaces to sanitize a brine barrel.
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5. You must at a minimum, have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for all production lots of ready-to-eat hot smoked fish products as evidenced by your failure to have sanitation monitoring documentation available during the inspection for a batch of whitefish fillets manufactured on 2/28/02.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the FDA's statute and regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action may include seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to David M. Kaszubski, Director of Compliance Branch, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260 ext. 185.

Sincerely,

  
Joann M. Givens  
District Director  
Detroit District Office

cc:

[REDACTED]