



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 20, 1997.

Our Reference No.: 29-51141

Scott H. Bradshaw, Owner
Fish Brothers Company
100 Ericson Court, Suite 140
Arcata, California 95521

WARNING LETTER

Dear Mr. Bradshaw:

An inspection of your seafood processing facility on August 12 and 14, 1997, by Food and Drug Administration (FDA) Investigator Jennifer King found serious violations of the Federal Food, Drug and Cosmetic Act, and the regulations for good manufacturing practices (GMP's) established in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). At the conclusion of the inspection, Investigator King presented a summary report to Production Manager Seth Meynell and discussed her observations with him. The report, Form FDA 483 (copy attached), included the following violations:

- Whole, raw albacore tuna was subject to time/temperature abuse in that the flesh attained temperatures between 49⁰ and 52.9⁰ fahrenheit after being held overnight to thaw without refrigeration, as follows:

A thermometer inserted approximately 3" deep in the loin area behind the gills on three tuna on a shelf revealed temperatures of 49.9⁰ F, 50.3⁰ F, and 52⁰ F.

A thermometer inserted approximately 3" deep in tail area of remaining three of eight tuna on a shelf revealed temperatures of 51.8⁰ F, 52.3⁰ F, and 52.9⁰ F.

Scott H. Bradshaw
Arcata, California

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- There is a lack of monitoring of the smoking and cooking of albacore tuna and salmon. The recording thermometer on the [REDACTED] fish smoker is inoperable during the cooking of the salmon, and the [REDACTED] smoker does not have a recording chart. No record is made of the time and temperature of cooking smoked salmon or smoked tuna in the two smokers.
- There is no sanitizer for utensils or food contact surfaces.

Tuna held at 50° F or higher for extended periods may be subject to decomposition and histamine formation. A food is adulterated under Section 402(a)(3) of the Act if it consists in whole or in part of a decomposed substance, or is otherwise unfit for food. Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Section 301(a) prohibits the introduction, or delivery for introduction, into interstate commerce of any adulterated food. The adulteration of food after receipt in interstate commerce is prohibited by Section 301(k).

All food manufacturing shall be conducted under such conditions and controls as necessary to minimize the potential for the growth of microorganisms. It is your responsibility to take appropriate steps to correct these violations on a permanent basis. Failure to do so could lead to adulteration of foods, processed and stored in your facility, within the meaning of Sections 402(a)(3) and/or 402(a)(4) of the Act.

Please advise this office in writing within fifteen (15) days of the receipt of this letter, of the specific steps you have taken to correct this situation and preclude any future recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which a correction will be completed. Your reply should be directed to Erlinda Figueroa, Compliance Officer.

Sincerely,



Charles D. Moss
Acting District Director
San Francisco District

Attachment: Form FDA 483