



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

HFI-35

m294n

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER

NWE-29-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 8, 1999

Francis P. Kulle
President
Lubec Packing Company
250 Commercial Street
Lubec, ME 04652

Dear Mr. Kulle:

On March 1 and 2, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 250 Commercial Street, Lubec, ME 04652. The investigators documented violations of Section 402 (a)(4) of the Federal Food Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR) Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation), as follows:

- ◆ Your HACCP plan did not list a food safety hazard that is reasonably likely to occur, as required by 21 CFR 123.6(b) and (c)(1)(vi). Specifically, your HACCP plan for canned Atlantic Herring (sardines) did not list the food safety hazard of histamine at the receiving critical control point.

On August 2-5, 1998 your Raw Fish Log documented receipt of Atlantic Herring, a histamine forming fish, at a temperature of [REDACTED] degrees Fahrenheit. Histamine has been known to form in histamine forming fish at these temperatures.

Your receiving critical control point does list decomposition and contamination as hazards requiring control. Monitoring for decomposition can be used to screen fish that have been subjected to a variety of abusive conditions. However, odors of decomposition that are typical of relatively low temperature spoilage may not be easily detected if the fish has undergone high temperature spoilage. Therefore, it cannot be used as the sole monitoring activity to control histamine formation. Monitoring at receipt and during storage of species such as Atlantic Herring, which can produce histamine, must ensure that the fish were not temperature abused during harvest, transport and storage. These monitoring activities can include but are not limited to the examination of vessel or carrier temperature control records, testing a representative sample of fish for histamine, and visual examination for ice or taking internal temperature of the fish.

- ◆ Your HACCP plan for Atlantic Herring does not list a critical control point, as required by 21CFR 123.6(b) and (c)(2). Specifically, your HACCP plan does not list the critical control point for the storage/holding tank stem after receipt for controlling the food safety hazard of histamine formation. On August 2-5, 1998 your Raw Fish Log documents holding of Atlantic Herring between [redacted] and [redacted] degrees Fahrenheit in tanks for [redacted] hours and [redacted] minutes to [redacted] hours and [redacted] minutes. As we explained above, histamine has been known to form in histamine forming fish at these temperatures and due to its inherent nature Atlantic Herring is a histamine forming fish.

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 federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions may include seizure and or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,

A handwritten signature in black ink, appearing to read "John Marzilli". The signature is written in a cursive style with a large initial "J".

John Marzilli
District Director
New England District Office