



DEC 21 2007

Dear Colleague:

This letter is intended to ensure that members of the low acid canned food (LACF) industry are aware of the Food and Drug Administration's (FDA's) serious concern about the under processing of canned food products which resulted in the recent recalls of hot dog chili sauce and canned French cut green beans. The under processing and consumption of canned food products present a serious public health risk of food poisoning resulting from the survival, outgrowth and toxin production of *C. botulinum* in such products.

The hot dog chili sauce outbreak resulted in people becoming seriously ill and hospitalized. The products showed no obvious outward signs of under processing, did not have an off odor or flavor, and appeared visually normal at the time they were consumed.

The scientific principles of canned food processing were established decades ago and FDA's canned food regulations are among the best examples of science-based food safety regulations with long records of successful implementation. Firms that produce low acid canned foods must not become complacent and must continually apply these time-proven scientific principles and ensure that their operations fully comply with FDA regulations, thereby reducing the risk of illness to consumers.

Foodborne outbreaks of illness attributed to consumption of low acid canned foods are rare. However, when they happen, they can result in significant public health and economic consequences. We believe that there are actions that can and should be undertaken immediately by the industry to address this issue. For example:

- Firms should ensure that all temperature distribution studies are current and that any change in the plumbing, steam supply, venting or spreader configuration of a retort be reviewed by a competent process authority before the retort is put into operation;
- Firms should thoroughly investigate the cause of spoilage and take immediate corrective actions;
- Firms operating thermal processing equipment in the manner prescribed in the regulations and their processing authorities should supply proper documentation and records in a timely manner upon request by FDA;
- Firms should thoroughly evaluate process deviations and provide records of these evaluations upon request during an FDA inspection.

The firms implicated in the recent outbreak and recalls are cooperating with the FDA, and are taking corrective action.

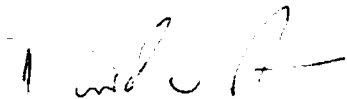
We encourage firms to take this opportunity to critically reexamine their operations and take appropriate measures to provide a safe product to the consumer. We are willing to work with the industry to ensure that this happens and thus enhance the safety of these products.

In addition to sending this letter, FDA is directing its field investigators that when conducting routine inspections of LACF firms, they should focus on the aforementioned preventive measures. We wish to remind you that firms that have been found to be operating outside the approved parameters may be subject to regulatory action, including being required to obtain an Emergency Permit from the FDA to continue processing.

We recognize and appreciate the extraordinary collaborative efforts by federal, state, and local authorities and industry to respond to the recent botulism outbreak, and provide a safe product to the U.S. consumer. We are confident that you will continue to work to achieve this goal.

If you have any questions regarding this letter, you may contact Donald Zink, Senior Food Scientist, Office of Food Safety by phone at 301-436-1693.

Sincerely yours,



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