



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 5, 1998

Mr. William Linding, President/CEO
Sysco Corporation
390 Enclave Blvd.
Houston, Texas 33308

Dear Mr. Linding:

On August 14 and 17, 1998, the Food and Drug Administration (FDA) conducted a reinspection of the Sysco Food Service facility at 71 Fuller Road in Albany, New York. Both this reinspection, and our previous inspection, performed March 23, 24 & 26, 1998, were conducted to assess compliance with FDA's seafood processing regulations (21 CFR 123) and Good Manufacturing Practice regulations (21 CFR 110). During both inspections our Investigator observed shortcomings that appear to be deviations from the principles of HACCP and the significant requirements of the program.

The seafood processing regulations, which became effective on December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrate to us, to Sysco customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During our March 23, 24 & 26, 1998 inspection of the Albany facility, we found its operations were not in compliance with the seafood processing regulations. The FDA Investigator provided a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the Inspectional Observations listing (FDA 483), to James T. Perko, Director of Operations. Those forms presented our evaluation of the facilities performance regarding various aspects of the HACCP requirements.

We were told by Mr. Perko the HACCP plans in use at his facility, and at other Sysco Food Service facilities, were supplied by Sysco headquarters at Houston, Texas. We were told the HACCP deficiencies would be brought to the attention of headquarters personnel, who would be commenting on the deficiencies and initiating corrective action. We subsequently issued a letter to Gail E. Allen who was identified to us as the President and most responsible person at the Albany facility. The letter, copy enclosed, pointed out the HACCP deficiencies found and asked for a written response to our office within thirty days. We received no response to that letter.

Our August 14 and 17, 1998 reinspection of the Albany facility again revealed deviations from the principles of HACCP and the significant requirements of the program. The Investigator again provided copies of forms FDA 3501 and FDA 483, this time directly to Gail E. Allen. Observations of concern found during the reinspection include the following:

1. Monitoring procedures in the HACCP plans for scombrototoxin (histamine) species of fish are inadequate for the critical control point "receiving". For example, HACCP plans for tuna loin skin-on boneless fresh, and for tuna loin boneless shushi grade, only require monitoring and documenting of either "THE TEMPERATURE OF THE PRODUCT UPON RECEIPT" *or* "THE QUANTITY OF ICE OBSERVED ON THE PRODUCT UPON RECEIPT". Because scombrototoxin formation is a significant hazard at the receiving step, and can result from time/temperature abuse, monitoring and documenting of *both* of the aforementioned criteria is required.
2. Failure to maintain records documenting the monitoring step of checking for adequate ice at the critical control point "Receiving" for scombrototoxin species of fish. Receiving records failed to indicate the results of an ice check for seven of thirty seven shipments received between 4/15/98 and 8/14/98 [21 CFR 123.6(c)(7)].
3. Failure to maintain records documenting the monitoring step of performing daily visual checks of the recorder thermometer chart used to measure ambient storage temperature at the critical control point "STORAGE" for scombrototoxin species of fish [21 CFR 123.6(c)(7)].
4. Failure to have the HACCP plans for tuna loin skin-on boneless fresh, and tuna loin boneless shushi grade, signed and dated by the most responsible individual onsite, or by a higher level official of the firm. The signature would signify the plan has been accepted for implementation at the firm [21 CFR 123.6(d)].

We noted similar deviations from the seafood HACCP requirements during our May 7&11, 1998 inspection of the Sysco Food Services facility located at 140 Wygant Road, Horseheads, New York. Although corrective action was promised verbally, we received nothing in writing and have not yet performed a reinspection to verify the adequacy of the corrective actions.

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We encourage you to have the necessary improvements made as soon as possible, at these and other seafood processing facilities under your control. However, if you disagree with FDA's assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the Agency should regard as complying with the regulations. We understand HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter within 30 working days of your receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with HACCP systems at your facilities. If we do not hear from you, or if your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule follow-up inspections for the immediate future.

Your reply relating to these concerns should be directed to the attention of James M. Kewley, Compliance Officer, at the above address. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to specific processes, you may contact Mr. Kewley by telephone at (716)551-4461 ext. 3128 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve successful HACCP programs in seafood processing facilities under your control.

Sincerely,



Brenda J. Holman
District Director

Enclosure: 5/14/98 ltr. to Gail E. Allen

JMK/sls

cc: Gail E. Allen, President & CEO
Sysco Food Services
P.O. Box 5327
Albany, NY 12205