Interpretation Number: 09-XI-.01-100

National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

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Model Ordinance Chapter I @.02 H.(2)(c)-(e)
Reference: Chapter XI 01.B.(2) and 01.C and 01.D
Chapter XII 01.B and 01.C
Chapter XIII 01.B.(2)
Chapter XIV 01.B and 01.C

Key Words: Time/Temperature abuse, Enforcement Follow-up, Microbiological testing

Question: Is microbiological testing by the shellfish control authority a suitable means of determining whether a critical deficiency exists when a dealer fails to control shellstock or shucked product time/temperature exposure during storage or processing as specified in the above referenced sections of Chapters XI, XII, XIII, and XIV. If such a critical deficiency exists, is microbiological testing (i.e. where the product may be released if no microbiological contaminants are found at or above levels of concern) a suitable enforcement follow-up?

Interpretation:

Failure to comply with the time/temperature exposure conditions specified in the referenced sections of the Guide for the Control of Molluscan Shellfish Chapters XI, XII, XIII, and XIV constitutes a critical deficiency. Chapter X. 0l. C. (2) and (3) states that, even if processors choose to select critical limits other than those specified in these referenced sections, they must meet the conditions as components of good manufacturing practice. Violation of the temperature control requirements is a critical deficiency. When a critical deficiency is observed, product must be controlled to prevent contaminated or adulterated shellfish from reaching consumers. Microbiological testing is not a suitable means of determining whether the deficiency is a critical deficiency. There are no provisions in the NSSP for any rating other than critical for such deficiencies.

The referenced sections of Chapter I state that when a critical deficiency is detected during an inspection, the dealer must correct the deficiency during the inspection and must cease production affected by the deficiency until the deficiency is corrected. Failing that, the Shellfish Control Authority must immediately begin certification suspension or revocation proceedings. Additionally the Authority is required to ensure that contaminated or adulterated product does not reach the consumer.

A suitable correction for a time/temperature abused product is destruction or processing the product in such a way that the microbiological hazard is eliminated (e.g. thermal processing) and modifying plant operations in such a way that a reoccurrence of the deficiency is not likely (e.g. pre-chilling product, reducing the size of the shucking or finished product containers, adding ice to the product during processing, making adjustments to or repairs to mechanical cooling systems). If these kinds of corrections are not enacted during the course of the inspection, the Shellfish Control Authority must immediately initiate certification revocation or suspension proceedings.

Microbiological testing (i.e. where the product may be released if microbiological contaminants are not found at or above levels of concern) is not a suitable means of ensuring that contaminated or adulterated product does not reach the consumer. The sample size necessary to ensure that any one microbiological contaminant is not present is prohibitively large, especially considering the low levels of organisms of concern and the typically high variability of the lot. Additionally, microbiological analysis will only provide information on the pathogen for which analysis was performed and low levels of indicator organisms is not a reliable assurance that pathogens are not present in the product.

Where the dealer fails to take the appropriate corrective action as outlined above and required by I.@.02 H.(2)(c), the shellfish Control Authority must initiate decertification procedures, as required by I.@.02 H.(2)(d), and must ensure that the product is removed from commerce or is processed to eliminate the hazard, consistent with I.@.02 H.(2)(e).

Rationale:

Shellfish is a potentially hazardous food, particularly since it is frequently consumed raw. Consequently, controls must be in place to prevent the growth of naturally occurring pathogens as well as pathogens that may be introduced into the product during processing. Rapid chilling and holding the product at refrigeration temperature are two of the most practical and effective means of controlling the microbial hazards in raw molluscan shellfish.

Naturally occurring Vibrio sp., such as *Vibrio vulnificus* and *Vibrio parahaemolyticus*, are human pathogens found in shellfish. During periods of warm water temperature, the number of these organisms may increase to high levels and further bioaccumulate in the shellfish during processing and storage. These organisms grow rapidly at temperatures of 70 degrees F or above (one log increase in 2 hrs). Conversely, little or no growth occurs at temperatures at or below 45 degrees F. Therefore, it is critical for shellfish products to be rapidly chilled to and held at 45 degrees F or less. Further, enteric pathogens may be introduced into the shellfish through improper handling during post harvest practices (e.g. use of contaminated water for shellstock washing or wet storage) or during shucking and repacking operations. Growth of these pathogenic organisms may also be prevented by rapidly chilling the product to 45 degrees F or less.

Other References:

1. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, Government Printing Office, Washington , DC

2. 21 Code of Federal Regulations, Part 110 - Current Good manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Government Printing Office, Washington , DC

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