

Proposal Subject: Re-submerging of shellstock

Specific NSSP Guide Reference: Model Ordinance Chapter V Section @.01 Paragraphs A and C; and Chapter V Section @.02 Paragraph B: Model Ordinance Chapter I. Purpose and Definitions

Text of Proposal/ Requested Action: Chapter I. Purpose and Definitions
Definitions.
Add new definition –

(92) Re-submerging means the process of short term submersion of shellstock in an approved growing area following initial harvest for purposes of reducing naturally occurring bacterial pathogens to background levels.

Renumber existing definitions 92 through 121.

Chapter V. Shellstock Relaying and Re-submerging

Section @.01 Paragraph A.

A. The shellstock:

- (1) ~~Used~~ Used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;
 - (2) Used in re-submerging activities is harvested from growing areas classified as approved or conditionally approved;
- B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;
- C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by the coliform group of indicator organisms ~~in the water~~, or naturally occurring pathogens such as *Vibrio* spp., or poisonous, or deleterious substances that may be present in shellstock to occur; and

Section @.02 Paragraph B

- A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.
- B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the relay or re-submerging activity:
- (1) The bacteriological quality of each shellfish species is the same bacteriological quality as that of the same species already present in the approved or conditionally approved area; or
 - (2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels; or
 - (3) The level of naturally occurring pathogens (*Vibrio* spp.) in each shellfish species is the same level of naturally occurring pathogens as that of the same species already present in the approved or conditionally approved area.

Public Health Significance: States that have a significant vibrio risk as determined by risk assessment have adopted requirements to limit the time between harvest and initial refrigeration.

Compliance with these time restrictions have created operational difficulties for various industry sectors and re-submerging oysters after initial harvest is being pursued as a means to mitigate vibrio growth during temperature abuse. However, the effectiveness of this approach for reducing Vibrios has not been demonstrated for the various approaches and practices that have been employed or proposed. This practice has the potential to greatly increase vibrio levels, especially if the oysters are unable to purge due to handling issues, transfer to different environmental conditions, gear type or over stacking. If the oysters are unable to pump, Vibrios will continue to grow at a rate determined largely by water temperature. While re-submerging has great potential to reduce vibrio levels, the best practices need to be determined and implemented.

**Cost Information
(if available):**

**Action by 2013
Task Force II** Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chairman.

**Action by 2013
General Assembly** Adopted recommendation of 2013 Task Force II on Proposal 13-209.

**Action by FDA
May 5, 2014** Concurred with Conference action on Proposal 13-209 with the following comments and recommendations.

FDA concurs with Conference action to refer Proposal 13-209 to committee. Proposal 13-209 requires that a study be conducted to ensure that shellstock transplanted or re-submerged, for purposes of mitigating levels of naturally occurring pathogens, are allowed sufficient time to reduce levels to background. While the intended purpose of re-submerging is to reduce naturally occurring pathogens such as *Vibrio* spp. to pre-harvest levels, re-submerging also has the potential to greatly increase *Vibrio* levels, especially if shellstock purging is limited as a result of environmental conditions, handling practices, over-stacking, etc. If shellstock cannot effectively pump, *Vibrio* levels will remain the same or possibly increase, depending on water temperature. While re-submerging can effectively reduce *Vibrio* levels, as demonstrated by FDA-ISSC studies conducted in 2013, effective application needs to be scientifically demonstrated.