Proposal No. **13-209**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Re-submerging of Shellstock
Specific NSSP Guide Reference	Section I. Purpose and Definitions Section II. Model Ordinance Chapter V. Shellstock Relaying
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 Requirements for the Authority @.01 General The Authority shall assure that: A. The shellstock: (1) ~~u~~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 D. If shellstock are relayed in containers: (1) The containers are: (a) Designed and constructed so that they allow free flow of water to the shellstock; and (b) Located so as to assure the contaminant reduction required in Section C.; and (2) The shellstock are washed and culled prior to placement in the containers. @.02 Contaminant Reduction 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 resubmerging 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 resubmerging oysters after initial harvest is being pursued as a means to mitigate Vibrio growth during temperature abuses. 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 resubmerging has great potential to reduce Vibrio levels, the best practices need to be determined and implemented.
Cost Information	
Action by 2013 Task Force II	Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chair.
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.
Action by 2015 Shellstock Resubmerging Committee	Recommended adoption of the following substitute language. Re-submerging means the process of short term submersion of shellstock following exceedance of the time temperature requirements of a vibrio control plan. The purpose of resubmerging is to allow shellstock harvested under conditions that are not compliant with Vibrio time temperature controls to return to background levels. Wet Storage means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or

	synthetic seawater at any permitted land-based activity or facility. Wet Storage can only be used for shellstock that is harvested under conditions that are compliant with the time temperature controls included in Chapter VIII. @.02. Chapter V. Shellstock Relaying and Resubmerging Add a new section Resubmerging. Renumber existing sections as appropriate. @.02 Resubmerging A. General. The Authority shall assure that: (1) The shellstock used in re-submerging activities is harvested from growing areas classified as approved, conditionally approved, restricted or conditionally restricted; (2) The level of contamination in the shellstock can be reduced to levels safe for human consumption; (3) The shellstock are held in growing areas classified as approved or conditionally approved, restricted, or conditionally restricted for a sufficient time under adequate environmental conditions so as to allow reduction of naturally occurring pathogens such as Vibrio spp. that may be present in shellstock to occur; and B. Natural Pathogen Reduction (1) 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. (2) 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 submerging activity. 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, conditionally approved, restricted or conditionally restricted area. (3) A study will not be required if shellstock remains in the growing area for a time period of at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.
Action by 2015 Task Force II	Recommended referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chairperson.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-209.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-209.