

Proposal Subject	Illness Outbreaks Associated with Consumption of Shellfish
Specific NSSP Guide Reference	NSSP Model Ordinance Chapter II. Risk Assessment and Risk Management @.01 Outbreaks of Shellfish-Related Illness
Text of Proposal/ Requested Action	<p>C. When the investigation outlined in @.01 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:</p> <ul style="list-style-type: none"> (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; (2) <u>When the investigation indicates the threat of illness is species specific, then a species-specific closure only may be instituted by the Authority and with concurrence from FDA.</u> (2)(3) Notify receiving states and the FDA that a potential health risk is associated with shellfish harvested from the implicated growing area; (3)(4) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and (4)(5) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations Part 7.
Public Health Significance	The basis for this addition is to allow the authority to limit closure of a growing area to specific shellfish species based on a risk assessment conducted by the Authority. This revision would allow the authority the ability to determine the epidemiological association between illness outbreak and shellfish consumption relative to shellfish species and their natural growing area characteristics, product handling, processing, and distribution without closing an entire growing area to all species. This approach would be similar to the Biotxin closure procedures.
Cost Information (if available)	Specific cost information has not been calculated as it would vary significantly by operation and location. The west coast industry and regulatory agencies, tribal and non-tribal, have all been parties to this effort and generally believe that this is a workable part of a solution to this concern.
Action by 2007 Task Force I	Recommended adoption of Proposal 07-100 as amended.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force I.
Action by USFDA	December 20, 2007 Concurred with Conference action.
G.	<p>Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the authority shall:</p> <ul style="list-style-type: none"> (1) <u>Shall</u> follow an existing marine biotoxin contingency plan, if appropriate. (2) <u>Shall</u> collect and analyze samples relevant to the investigation, if appropriate. (3) <u>Shall</u> keep the area closed until it has been determine that levels of naturally occurring pathogens and/or biotoxins are not a public health concern. (4) <u>May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.</u>