

	<p><b>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</b></p>	<p>a. <input checked="" type="checkbox"/> Growing Area  b. <input type="checkbox"/> Harvesting/Handling/Distribution  c. <input type="checkbox"/> Administrative</p>
Submitter	ISSC Male-Specific Coliphage Committee	
Affiliation	Interstate Shellfish Sanitation Conference	
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Proposal Subject	Utilizing Male-Specific Coliphage in Growing Areas	
Specific NSSP Guide Reference	Section I. Purpose and Definitions  Section II. Model Ordinance Chapter IV. Shellstock Growing Area and Chapter V. Shellstock Relaying	
Text of Proposal/ Requested Action	<p><b>Section I. Purpose and Definitions</b></p> <p>Add new definitions:</p> <p><u><b>Wastewater Treatment Plant (WWTP)</b> means a facility that treats or removes contaminants from sanitary and industrial sewage through a combination of processes to a point where it can be discharged to the environment or reclaimed for other purposes.</u></p> <p><u><b>Wastewater Collection System</b> means a collection system which may comprise of sanitary sewer pipes, or a combination of sanitary sewer pipes and stormwater pipes, and pump stations to ensure that disposed wastewater is delivered to the wastewater treatment plant to be treated.</u></p> <p><u><b>Wastewater Treatment Plant Design Flow</b> means the flow that the WWTP is designed to discharge over a specified time period (such as hourly, daily, monthly, or annually) and typically expressed as a daily or hourly average with the expectation of meeting permit requirements</u></p> <p><b>Section II. Model Ordinance</b>  <b>Chapter IV. Shellstock Growing Areas</b></p> <p><b>@.02 Microbiological Standards.</b></p> <p>A. General...  B. Water Sample Stations...  C. Exceptions...  D. Standard for the Approved....  E. Standard for the Approved Classification of Growing Areas Affected By Point Sources.</p> <p>(1) Water Quality. The bacteriological quality of every station in</p>	

the growing area shall meet the fecal coliform standard in Section E. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (10) percent of the samples shall exceed an MPN or MF(mTEC) of:

- (a) 43 MPN per 100 ml for a five-tube decimal dilution test;
- (b) 49 MPN per 100 ml for a three-tube decimal dilution test;
- (c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
- (d) 31 CFU per 100 ml for a MF (mTEC) test.

(e) For SSCA utilizing MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts, the MSC level shall not exceed fifty (50) MSC per hundred (100) grams.

(3) Required Sample Collection.

- (a) A minimum of five (5) samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.
- (b) A minimum of the most recent fifteen (15) samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric mean and percentage to determine compliance with this standard.
- (c) Sample station locations shall be adjacent to actual or potential sources of pollution.

- F. Standard for the Approved...
- G. Standard for the Restricted...
- H. Standard for the Restricted...

**@.03 Growing Area Classification.**

A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.

- (1) Emergency Conditions..
- (2) Classification of All Growing Areas...
- (3) Boundaries...
- (4) Revision of Classifications...
- (5) Status of Growing Areas... The status of a growing area is separate and distinct from its classification and may be open, closed or inactive for the harvesting of shellstock.
  - (a) Open Status...
  - (b) Closed Status...
  - (c) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:
    - (i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious

	<p>substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or</p> <p>(i) For emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or Waste Water System Discharge (WWSO), the analytical sample results shall not exceed <del>the a-levels established in Chapter IV @ 02. E of fifty (50) male specific coliphage per 100 grams</del> or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted or until the event is over and 21 days have passed; or</p> <p>(iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and</p> <p>(iv) Supporting information is documented by a written record in the central file.</p> <p>(d) Inactive Status...</p> <p>(e) Remote Status...</p> <p>(f) Seasonally Remote/Approved Status...</p> <p>B. Approved Classification...</p> <p>C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:</p> <p>(1) Survey Required...</p> <p>(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:</p> <p>(a) For management plans based on wastewater treatment plant function, performance standards that include:</p> <p>(i) Peak effluent flow, average flow, and infiltration flow;</p> <p>(ii) Microbiological quality of the effluent;</p> <p>(iii) Physical and chemical quality of the effluent;</p> <p>(iv) Conditions which cause plant failure;</p> <p>(v) Plant or collection system bypasses;</p> <p>(vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;</p> <p>(vii) Provisions for monitoring and inspecting the waste water treatment plant; and</p> <p>(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;</p> <p>(b) For management plans based on pollution sources other than waste water treatment plants:</p>
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	<p>(i) Performance standards that reliably predict when criteria for</p> <p>(ii) Discussion and data supporting the performance standards.</p> <p>(c) For management plans based on waste water system discharge function or pollution sources other than waste water system discharge criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:</p> <p>(i) Performance standards of the plan are fully met;</p> <p>(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;</p> <p>(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water. The SSCA may utilize <u>MSC levels to establish that sufficient time has elapsed to allow the water quality to return to acceptable levels</u> in growing areas adjacent to waste water system discharge. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. Analytical sample results shall not exceed <u>the MSC levels established in Chapter IV @02 E. a level of 50 MSC per 100 grams</u> or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in the shellfish meats or the area must be in the closed status until the event is over and twenty-one (21) days have passed; and</p> <p>(iv) Shellstock feeding activity is sufficient to achieve microbial reduction.</p> <p>(d) For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;</p> <p>(e) For management systems based on marine Biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;</p> <p>(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;</p> <p>(g) Provisions for patrol to prevent illegal harvest; and</p> <p>(h) Procedures to immediately place the growing area in the</p>
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	<p>closed status in 24 hours or less when the criteria established in the management plan are not met.</p> <p>(3) Reevaluation of Conditional Classification...</p> <p>(4) Understanding of and Agreement With...</p> <p>(5) Conditional Area Types...</p> <p>(6) Conditionally Approved Classification...</p> <p>(7) Conditionally Restricted Classification...</p> <p>D. Restricted Classification...</p> <p>E. Prohibited Classification...</p> <p><b>Chapter V. Shellstock Relaying</b></p> <p><b>@.02 Contaminant Reduction.</b></p> <p>A. The Authority shall ...</p> <p>B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity:</p> <p>(1) The microbiological quality of each shellfish species is the same microbiological quality as that of the same species already present in the approved or conditionally approved area; or</p> <p>(2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels; or</p> <p>(3) When the source growing area is impacted by waste water system discharge, the viral quality of each shellfish species meets the male-specific coliphage <u>(MSC) levels established in Chapter IV @02.E. standard of 50 PFU/100 gm</u> or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions.</p> <p>C. The authority may...</p> <p>D. The time period...</p> <p>E. When container relaying...</p> <p>F. The Authority shall...</p>
<p>Public Health Significance</p>	<p>In 2015, the ISSC adopted proposal 15-102 which incorporated the use of Male Specific Coliphage into the Nssp. The ISSC voting delegates directed the development of a guidance document to provide clarification for the use of MSC. In the development of the guidance document, the MSC Committee concluded to changes were needed in Chapter IV for clarification and consistency. The proposed changes do not change the requirements of Chapter IV.</p>
<p>Cost Information</p>	