Proposal No. 15-102

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting		 a. ⊠ Growing Area b. □ Harvesting/Handling/Distribution c. □ Administrative 			
Submitter	Growing Area Classification Committee				
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)				
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Proposal Subject	Using Male-Specific Coliphage as a Tool to Refine Determinations of the Size of				
Transfer in the second	the Areas to be Classified as Prohibited Adjacent to Each Outfall				
Specific NSSP	Section II. Model Ordinance				
Guide Reference	Chapter IV. Shellstock Growin	ng Areas			
Text of Proposal/	@.01 Sanitary Survey.	-6			
Requested Action	A. General.				
	environment sources, wh growing are results of: (a) A show the way system may usample the sare (c) An eydroogrowing (d) An a the meteo (e) A de	y survey is the written evaluation report of all tal factors, including actual and potential pollution eich have a bearing on water quality in a shellfish ea. The sanitary survey shall include the data and reline survey; very of the bacteriological microbiological quality of ater and in growing areas adjacent to wastewater in discharges the State Shellfish Control Authority utilize MSC results from analysis of shellfish meat ees and the analysis of the data will be included in initary survey report; evaluation of the effect of any meteorological, dynamic, and geographic characteristics on the ing area; nalysis of the data from the shoreline survey, bacteriological and the hydrodynamic, rological and geographic evaluations; etermination of the appropriate growing area fication.			
	B. Sanitary Survey RequiredC. Sanitary Survey Performance.				
	(5) On an annual changes in reevaluation	basis, the sanitary survey shall be updated to reflect the conditions in the growing area. The annual shall include: Id observation of the pollution sources which may			

- (b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in Section .02;
- (c) Review of available inspection reports and effluent samples collected from pollution sources;
- (d) Review of available performance standards for various types of discharges that impact the growing area; and
- (e) A brief report which documents the findings of the annual reevaluation-; and
- (f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of waste water system discharge (WWSD) impacts on shellfish growing areas.
- (g) If MSC meat and/or water data is being used, the SSCA shall conduct annual sample collection and analysis in determining performance standards.
- D. Shoreline Survey Requirements...

@.02 Bacteriological Microbiological Standards.

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. The NSSP also allows for two (2) sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two (2) ways: a total coliform strategy and a fecal coliform strategy so that the state may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, a state may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards. Additionally, states may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by waste water system discharges.

- <u>A.</u>. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. <u>The SSCA may utilize MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts on shellfish growing areas.</u>
- B. Water Sample Stations...
- C. Exceptions...
- D. Standards for the Approved Classification of Growing Areas in the Remote Status...
- E. Standard for the Approved Classification of Growing Areas Affected by Point Sources...
- F. Standard for the Approved Classification of Growing Areas Affected by

- Nonpoint Sources...
- G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration...
- H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration...

@.03 Growing Area Classification.

A. General...

- (1) Emergency Conditions...
- (2) Classification of All Growing Areas...
- (3) Boundaries...
- (4) Revision of Classifications...
- (5) Status of Growing Areas...
 - (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 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 preclosure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or
 - (ii) For emergency closures (not applicable for conditional closures) of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or wastewater treatment plant, the analytical sample results shall not exceed background levels or a level of fifty (50) male-specific coliphage per 100 grams 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
 - (iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and
 - (iv) Supporting information is documented by a written record in the central file.
 - (d) Inactive Status...

- (e) Remote Status...
- (f) Seasonally Remote/Approved Status...
- B. Approved Classification...
- C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:
 - (1) Survey Required. The sanitary survey meets the following criteria:
 - (a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;
 - (b) Each potential source of pollution that may adversely affect the growing area is evaluated;
 - (c) <u>Bacteriological Microbiological</u> water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and
 - (d) For SSCAs utilizing MSC meat sample data, this data correlates with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.
 - (2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:
 - (a) For management plans based on wastewater treatment plant function, performance standards that include:
 - (i) Peak effluent flow, average flow, and infiltration flow:
 - (ii) Microbiological quality of the effluent;
 - (iii) Physical and chemical quality of the effluent;
 - (iv) Conditions which cause plant failure;
 - (v) Plant or collection system bypasses;
 - (vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
 - (vii) Provisions for monitoring and inspecting the waste water treatment plant; and
 - (viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;
 - (b) For management plans based on pollution sources other than waste water treatment plants:
 - (i) Performance standards that reliably predict when criteria for conditional classification are met; and
 - (ii) Discussion and data supporting the performance standards.
 - (c) For management plans based on waste_water system discharge treatment plant function or pollution sources other than waste_water system_discharge treatment plants, criteria that reliably predict when an area that was placed in the closed status because of failure to comply

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with its conditional management plan can be returned to the open status. The minimum criteria are:

- (i) Performance standards of the plan are fully met;
- (ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
- (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; and
- For Conditional Management Plans based on (iv) waste water system discharge performance and for SSCAs utilizing MSC, 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 viral levels in the shellstock. Analytical sample results shall not exceed background levels or a level of 50 MSC per 100 grams. The study 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
- (v) Shellstock feeding activity is sufficient to achieve coliform-microbial reduction.
- (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;
- (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;
- (f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;
- (g) Provisions for patrol to prevent illegal harvest; and
- (h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.
- (3) Reevaluation of Conditional Classification...
- (4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved...
- (5) Conditional Area Types...
- (6) Conditionally Approved Classification...

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- (7) Conditionally Restricted Classification...
- D. Restricted Classification...
- E. Prohibited Classification.
 - (1) Exception...
 - (2) General...
 - (3) Sanitary Survey...
 - (4) Risk Assessment...
 - (5) Wastewater Discharges.
 - (a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.
 - (b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:
 - (i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent;

 The SSCA may utilize MSC wastewater sample data in the determination of the performance of the sewage treatment plant;
 - (ii) The decay rate of the contaminants of public health significance in the wastewater discharged;
 - (iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and
 - (iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

NOTE:

All references in Section II. Model Ordinance Chapter IV. Shellstock Growing Areas will be changed to Waste Water System Discharge (WWSD).

13. Public Health Significance

Male-specific Coliphage (MSC) is a RNA virus of E. coli present in high numbers in raw sewage (on the order of 105 PFU/100gm). MSC is similarly resistant to chlorine disinfection as are norovirus and hepatitis A viruses, which are the viral pathogens of concern in sewage. MSC is a good surrogate or marker for these enteric viruses and is a powerful tool to assess the impact on a growing area of raw, partially treated and treated sewage on adjacent growing areas.

A better assessment of the risk of viral contamination at a particular location in an adjacent growing area can be ascertained directly using MSC assays of the shellstock. Performing and evaluating dye studies on waste water treatment plant outfall_discharges, although effective, is expensive and complicated. Difficulties assessing ex-filtration and leakage from the sewage collection system are well known. Few tools and less guidance are available to adequately assess the performance of a particular waste water treatment plant design and its operation with respect to virus removal. There are advantages of using this specialty viral indicator to assess the overall impact of a municipal wastewater treatment system on a particular growing area.

The ISSC held an MSC meeting in Charlotte on August 18-19, 2014 to discuss the

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	available MSC science and knowledge. A panel of MSC experts provided MSC information and consensus regarding usage of MSC in the NSSP. (Click here to view, download, or print the MSC meeting report).				
14. Cost Information	The use of MSC is not a requirement; rather, it is an option for States to use, so there would be no cost to States who do not choose to use it. For States that do choose to use MSC, the cost is discussed in the ISSC MSC Meeting Report, August 18-19, 2014, where it states: The MSC assay for shellfish is relatively easy to perform and the cost is roughly equivalent to that of performing fecal coliform testing. The initial cost to prepare laboratory to perform analysis, depends on the lab, and may be approximately \$8000 to \$10,000, if additional equipment is needed. There may also be cost associated with sample collection.				
Action by 2015	Recommended adoption of Proposal 15-102 as amended.				
Task Force I	@.01 Sanitary Survey. A. General.				
	 (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of: (a) A shoreline survey; (b) A survey of the microbiological quality of the water and in growing areas adjacent to wastewater system discharges the State Shellfish Control Authority may utilize MSC results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report; (c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area; (d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations; (e) A determination of the appropriate growing area classification. 				
	B. Sanitary Survey Required				
	C. Sanitary Survey Performance. (5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include: (a) A field observation of the pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; and (iii) Information from other sources.				
	(iii) Information from other sources. (b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection				

- required in Section .02;
- (c) Review of available inspection reports and effluent samples collected from pollution sources;
- (d) Review of available performance standards for various types of discharges that impact the growing area;
- (e) A brief report which documents the findings of the annual reevaluation; and
- (f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of waste water system discharge (WWSD) impacts on shellfish growing areas.
- (g) If MSC meat and/or water data is being used, the SSCA shall conduct annual sample collection and analysis in determining performance standards.
- D. Shoreline Survey Requirements...

@.02 Microbiological Standards.

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. The NSSP also allows for two (2) sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two (2) ways: a total coliform strategy and a fecal coliform strategy so that the state may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, a state may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards. Additionally, states may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by waste water system discharges.

- A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The SSCA may utilize MSC data in conjunction with bacteriological data to evaluate waste water system discharge (WWSD) impacts on shellfish growing areas.
- B. Water Sample Stations...
- C. Exceptions...
- D. Standards for the Approved Classification of Growing Areas in the Remote Status...
- E. Standard for the Approved Classification of Growing Areas Affected by Point Sources...
- F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources...
- G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration...

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration...

@.03 Growing Area Classification.

A. General...

- (1) Emergency Conditions...
- (2) Classification of All Growing Areas...
- (3) Boundaries...
- (4) Revision of Classifications...
- (5) Status of Growing Areas...
 - (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 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 preclosure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or
 - For emergency closures of harvest areas caused (ii) by the occurrence of raw untreated sewage discharged from a large community sewage collection system or wastewater treatment plant, the analytical sample results shall not exceed background levels or a level of fifty (50) malespecific coliphage per 100 grams or predetermined 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 day have passed; or
 - (iii) The requirements for Biotoxins or conditional area management plans as established in Section .04 and Section .03, respectively, are met; and
 - (iv) Supporting information is documented by a written record in the central file.
 - (d) Inactive Status...
 - (e) Remote Status...

- (f) Seasonally Remote/Approved Status...
- B. Approved Classification...
- C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:
 - (1) Survey Required. The sanitary survey meets the following criteria:
 - (a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;
 - (b) Each potential source of pollution that may adversely affect the growing area is evaluated;
 - (c) Microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and
 - (d) For SSCAs utilizing MSC meat sample data, this data correlates with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.
 - (2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:
 - (a) For management plans based on wastewater treatment plant function, performance standards that include:
 - (i) Peak effluent flow, average flow, and infiltration flow:
 - (ii) Microbiological quality of the effluent;
 - (iii) Physical and chemical quality of the effluent;
 - (iv) Conditions which cause plant failure;
 - (v) Plant or collection system bypasses;
 - (vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
 - (vii) Provisions for monitoring and inspecting the waste water treatment plant; and
 - (viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;
 - (b) For management plans based on pollution sources other than waste water treatment plants:
 - (i) Performance standards that reliably predict when criteria for conditional classification are met; and
 - (ii) Discussion and data supporting the performance standards.
 - (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:

- (i) Performance standards of the plan are fully met;
- (ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
- (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;
- (iv) For Conditional Management Plans based on waste water system discharge performance and for SSCAs utilizing MSC, 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 viral levels in the shellstock. Analytical sample results shall not exceed background levels or a level of 50 MSC per 100 grams or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studiesy 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
- (v) Shellstock feeding activity is sufficient to achieve microbial reduction.
- (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;
- (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;
- (f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;
- (g) Provisions for patrol to prevent illegal harvest; and
- (h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.
- (3) Reevaluation of Conditional Classification...
- (4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved...

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		(F) C - 1	1:4: au - 1 A	T	
	(5) Conditional Area Types				
	(6) Conditionally Approved Classification				
	(7) Conditionally Restricted Classification				
	D. Restricted Classification				
	E. Prohibited Classification.				
	(1) Exception				
	(2) General				
	(3) Sanitary Survey				
	(4) Risk Assessment				
	(5) Wastewater Discharges.				
	(a) An area classified as prohibited shall be established				
		(4.)	adjacer	nt to each sewage treatment plant outfall or any	
				oint source outfall of public health significance.	
		(b)		termination of the size of the area to be classified hibited adjacent to each outfall shall include the	
				ng minimum criteria:	
			(i)	The volume flow rate, location of discharge,	
			(1)	performance of the wastewater treatment plant	
				•	
				and the microbiological quality of the effluent; The	
				SSCA may utilize MSC wastewater sample	
				data in the determination of the performance of	
			/** \	the sewage treatment plant;	
			(ii)	The decay rate of the contaminants of public health significance in the wastewater discharged;	
			(iii)	The wastewater's dispersion and dilution, and	
			(111)	the time of waste transport to the area where	
				shellstock may be harvested; and	
			(iv)	The location of the shellfish resources,	
			(11)	classification of adjacent waters and	
				identifiable landmarks or boundaries.	
				identifiable fandhafks of boundaries.	
	NOTE: All references in Section II. Model Ordinance Chapter IV. Shell				
	NOIE.			^	
	Growing Areas will be changed to Waste Water System Discharge				
A .: 1 2017	A 1 . 1	(WWSD)		1 F I D 117 100 11 6 1	
Action by 2015	Adopted recommendation of Task Force I on Proposal 15-102 with referral to an				
General Assembly	appropriate committee as determined by the Conference Chair to develop a draft				
	guidance document which will be presented to the ISSC Executive Board at the				
	2016 spring meeting for interim approval.				
Action by FDA					
January 11, 2016	Concurred w	vith Confe	rence act	ion on Proposal 15-102.	