

<b>Proposal Subject:</b>	Re-opening Conditional Areas using Male-specific Coliphage after WTP Malfunction
<b>Specific NSSP Guide Reference:</b>	NSSP 2009 Section II Model Ordinance Chapter IV Shellstock Growing Areas @ .03 Growing Area Classification A. (5) (c) (ii)
<b>Text of Proposal/ Requested Action</b>	(ii) For emergency closures ( <del>not applicable for conditional closures</del> ) of harvest areas caused by the occurrence of raw untreated sewage or <u>partially treated sewage</u> 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 50 male-specific coliphage per 100 grams from shellfish samples collected no sooner than 7 days after contamination has ceased and from representative locations in each growing area potentially impacted; or
<b>Public Health Significance:</b>	Male-specific Coliphage (MSC) is an RNA virus of E. coli present in high numbers in raw sewage (on the order of 10 <sup>5</sup> PFU/100gm). MSC is similarly resistant to chlorine disinfection as are norovirus and hepatitis A viruses, which are the viral pathogens of primary concern in sewage. MSC is a good surrogate or marker for these enteric viruses. Raw or partially treated sewage accidentally discharged into a growing area by sewage bypass from pump station failures, broken sewage lines, or malfunctions at the wastewater treatment facilities represent a serious public health risk and require emergency closure of adjacent conditional growing areas. These closures are typically 21 days after the wastewater treatment system returns to normal operation. Recent work has shown that persistence of viruses in the growing waters is much lower in the summer months than in the winter months. Likewise, bio-accumulation rates and retention of enteric viruses in molluscan shellfish is much lower in the summer months than the winter months. MSC can be a useful tool for state shellfish programs to mitigate the negative effect of prolonged conditional closures due to wastewater treatment system failures. This approach is most appropriate in the late-spring and summer months to shorten these closures from 21 to 7 days.
<b>Cost Information (if available):</b>	The Male-specific Coliphage (MSC) Method is an inexpensive double-agar pour plate method that can be run in any state-certified microbiological laboratory. A refrigerated centrifuge capable of 9,000G is required which costs \$10K to \$12K (USD). Re-opening after 7 days using MSC method is optional for state shellfish control agencies.
<b>Action by 2011 Task Force I</b>	Recommended referral of Proposal 11-101 to the appropriate committee as determined by the Conference Chairman. FDA is requested to prepare and provide MSC data from wastewater treatment plant sampling to the committee. FDA is further requested to involve the submitter in this proposal in analyzing that data.
<b>Action by 2011 General Assembly</b>	Adopted recommendation of 2011 Task Force I on Proposal 11-101.
<b>Action by FDA February 26, 2012</b>	FDA concurred with Conference action on Propposal 11-101 with the following recommendations.  FDA concurs with Conference action to refer Proposal 11-101 to an appropriate committee as determined by the Conference Chairperson. The intent of these Proposals is to expand the application of Male Specific Coliphage (MSC) for use in the management of conditional areas affected by raw or partially untreated sewage discharges from wastewater treatment plants (WWTP) or community sewage collection systems and for assessing the impact of WWTP discharges and/or sewerage collection system leaks in determining the size of adjacent areas for classification as conditionally

restricted or conditionally approved. Presently, however, there is insufficient data from which to make sound science based decisions regarding the use of MSC as a more comprehensive tool for growing area management.

Support for using MSC for conditional area management is based on uptake and elimination data for a single shellfish species, soft-shelled clams (*Mya arenaria*), impacted by effluent from a highly efficient WWTP at one geographic location over just one harvest season. Those data are not adequate to ensure the efficacy of MSC to safely manage other conditional areas for other species of shellfish, in other geographic regions, and over other seasons.

Careful consideration needs to be given to the fact that a WWTP malfunction is often a consequence of adverse weather conditions, most notably excessive rainfall over short periods. Such rainfall events usually cause excessive land based runoff, carrying non-point fecal pollution to conditional areas. While MSC are generally ubiquitous in municipal wastewater, that is not the case with smaller pollution sources. For this reason MSC are inappropriate for indexing smaller sources and do not lend themselves well to managing areas subject to pollution from both WWTPs and other sources. Shellfish associated norovirus (NoV) outbreaks investigated by FDA's Gulf Coast Seafood Laboratory (GCSL) in the past several years have, in nearly all instances, shown MSC levels in shellfish below the assay's sensitivity (< 10 pfu/100ml), while testing positive for NoV. These results indicate that the source of NoV was not from a WWTP. Though MSC appear to have utility and promise in assessing potential viral contamination in shellfish, much remains to be learned about their prevalence and ability to reliably index fecal contamination from various sources of human sewage.

Several approaches for generating additional information and data needed to better define how MSC could potentially be used for growing area management and classification include:

- Continued studies to examine the uptake and elimination of NoV, enterovirus, and MSC by shellfish species other than soft-shelled clams. These investigations should be conducted in multiple geographic locations representative of the country and over all seasons.
- A SL V has been conducted and adopted by the ISSC for the method to enumerate SC in soft-shelled clams and oysters. A SL V is needed to demonstrate the efficacy of this or another method to enumerate MSC in other species of shellfish.
- Understanding the efficiency of various wastewater treatment systems to inactivate/remove enteric viruses prior to discharge.
- Continued studies to examine and compare MSC and enteric virus levels in wastewater influent and effluent, shellfish receiving waters, and shellfish.

As requested by Task Force I, information is currently being compiled by FDA regarding MSC data from WWTP sampling. Those data should be available to the ISSC in March, 2012.