

Proposal Subject:	Re-Opening Conditional Areas using Male-Specific Coliphage after WTP Malfunction
Specific NSSP Guide Reference:	NSSP Guide Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @ .03 A. (5) (c) (ii)
Text of Proposal/ Requested Action	<p>@ .03 Growing Area Classification</p> <p>A. General</p> <p>(5) Status of Growing Areas</p> <p>(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:</p> <p>(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 <u>and no later than twenty-one (21) days</u> after contamination has ceased and from representative locations in each growing area potentially impacted <u>provided that water temperatures exceed 45° F</u>; or</p>
Public Health Significance:	<p>Raw or partially treated sewage accidentally discharged into a growing area by sewage by-pass 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.</p> <p>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 may be a good surrogate for enteric viruses.</p> <p>Recent work has shown that persistence of viruses in the growing waters is much lower in the summer months than in the winter months. Depuration rates of enteric viruses in molluscan shellfish is also faster in summer months. MSC can be a useful tool for state shellfish programs to mitigate the negative effect of prolonged conditional closures due to WTP system failures. This approach has been shown to work well in late-spring and summer months to shorten these closures from 21 to as short as 7 days.</p> <p>Most of the validation work developing this assay has been done using soft-shelled clams and oysters, during months when temperatures are above 50°F. Relatively little work on the use of this assay has been done using hard clams or when temperatures fall below 50°F. Until the assay has been appropriately validated for other shellfish species such as hard-shelled clams, and a sound correlation between MSC and enteric viruses of concern such as Norwalk virus over a range of temperatures, use of this assay on hard clams and in cold waters may result in unnecessarily prolonged closures not correlated with a real public health risk.</p> <p>Consider also the comments on proposal 11-102 by the FDA: <i>“Support for using MSC for conditional area management is based on uptake and</i></p>

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.” (emphasis added) and also: “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.”

For several decades emergency closures have lasted for 21 days after the WTP system returns to normal operation. This practice was not associated with reports of illness associated with enteric viruses.

Some states have investigated using the MSC assay to assist in speeding the reopening of waters following emergency closures, however persistent high levels have led some states to resist implementation of the MSC assay. Following Hurricane Sandy some states shipped shellfish despite high MSC counts and no illnesses were reported (Keith Skiles, personal communication).

**Cost Information
(if available):**

The Male-specific Coliphage (MSC) Method is an inexpensive double-agar pour plate method, which can be run in any state-certified microbiological laboratory. A refrigerated centrifuge capable of 9,000G is required which cost \$10K to \$12K (US dollars). Re-opening after 7 days using MSC method is optional for the State shellfish control agency.

**Action by 2013
Task Force I**

Recommended no action on Proposal 13-104.

Rationale: Limiting the sample collection to no later than twenty-one days could restrict SSCAs from gathering important data that could be used to evaluate the risk of further illnesses.

**Action by 2013
General Assembly**

Adopted recommendation of 2013 Task Force I on Proposal 13-104.

**Action by FDA
May 5, 2014**

Concurred with Conference action on Proposal 13-104.