

<b>Proposal Subject:</b>	Using Male-specific Coliphage as a Tool to Refine Determinations of the Size of the Areas to be Classified as Prohibited Adjacent to Each Outfall
<b>Specific NSSP Guide Reference:</b>	NSSP 2009 Section II Model Ordinance Chapter IV Shellstock Growing Areas @.03 Growing Area Classification E. (5)
<b>Text of Proposal/ Requested Action</b>	<u>(c) An assessment of the combined impact of waste water treatment plant outfall and/or ex-filtration (leakage) from sewerage collection systems may be performed using male-specific coliphage assays on shellstock from adjacent growing areas. A male-specific coliphage standard of &lt; 50 PFU/100gm in shellfish meats may be used as the basis for the determination of the size of the adjacent area to be classified as conditionally restricted or approved.</u>
<b>Public Health Significance:</b>	<p>Male-specific Coliphage (MSC) is a RNA virus of E. coli present in high numbers in raw sewage (on the order of <math>10^5</math> 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. US and EU studies show that during the summer months MSC and associated pathogenic enteric viruses are at seasonal lows. Conversely, the risk of viral disease transmission is significantly higher in the winter months as evidenced by epidemiological studies as well as studies conducted using MSC and molecular detection of target pathogens.</p> <p>A better assessment of the risk of viral contamination at a particular location in an adjacent growing area at a particular time of year can be ascertained directly using MSC assays of the shellstock. Performing and evaluating dye studies on waste water treatment plant outfall evaluation 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. The advantages of using this specialty viral indicator to assess the overall impact of a municipal wastewater treatment system on a particular growing area are many. In growing areas impacted by waste water treatment systems, positive norovirus detected by molecular methods at significant levels in the shellfish are accompanied by corresponding high levels of MSC. MSC assays are a direct and straightforward method to determine the viral risk or validate traditional assessment techniques.</p>
<b>Cost Information (if available):</b>	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 costs \$10K to \$12K (USD). Cost savings and a higher level of public health protection may be realized using MSC assays of shellfish verses the level of effort needed to ascertain the viral risk indirectly through dye studies, 1000:1 dilution line determinations and performance evaluations.
<b>Action by 2011 Task Force I</b>	Recommended referral of Proposal 11-102 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 11-102.