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Proposal Subject Alternative Male-specific Coliphage Meat Standard for Restricted Classification of Growing Areas Impacted by wastewater treatment plant outfall.

Specific NSSP Section II. Model Ordinance  
Guide Reference Chapter IV. Shellstock Growing Area @ .02 Bacteriological Standards

Text of Proposal/  
Requested Action G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(4) Exception.  
If the Male-specific Coliphage indicator is used for supplemental process verification using an end-point meat standard of < 50PFU/100gm and existing fecal coliform testing requirements in Chapter XV .03 J. are used, then FC water quality monitoring is not required for the restricted classification of growing areas affected by point sources such as wastewater treatment plant outfall.

Public Health Significance Under shellfish relay, water quality requirements are not needed for the restricted classification when a contaminant reduction study is conducted and a minimum time period of two weeks is used. For depuration, the restricted classification requires water quality monitoring and standards. The reason for these upper FC limits is that FC meat indicator does not adequately reflect the viral risk and/or viral depuration kinetics. Male-specific coliphage is a viral indicator organism to be used in growing areas impacted by point source sewage contamination. MSC demonstrates significant advantages over FC alone for both the assessment of viral contamination and assessment of viral depuration kinetics. Upper FC limits were put into the NSSP to prevent shellfish with higher levels of viruses from being depurated. Several studies clearly show that conventional depuration using FC for process validation is not adequate to protect public health with respect to virus contamination in growing areas with significant wastewater treatment plant and sewage impact. Studies have also shown that viral levels in shellfish impacted by sewage and partially treated sewage detected using MSC and molecular techniques are much lower in the summer months than the winter months. Additionally, the viral depuration rate is higher in the summer with process waters >18°C. Recent studies have also shown that MSC is an appropriate viral indicator to assess viral depuration. Therefore, seasonal viral depuration using male-specific coliphage as well as FC for process verification is a superior approach to taking water samples using FC in a growing area adjacent to wastewater treatment plant outfall. Combining the bacterial indicator of FC and the viral indicator MSC for mitigation strategies that use meat scores is far more direct and effective than water quality sampling in this context.

Cost Information 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). Significant cost savings and a higher level of public health protection may be realized using strategies such as seasonal coliphage depuration process validated using MSC and seasonal coliphage relay using MSC in contaminant reduction studies than requiring

water quality limits using FC.

Action by 2011 Task Force I Recommend referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-103.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-103.

Action by 2013 Growing Area Classification Committee Recommend referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman.

It was additionally recommended that a workgroup be formed to look at current MSC data and the science behind its potential use and applicability for use in the NSSP. The workgroup will organize a summit of outside experts, academia, and scientists to present current information and science on MSC. The group will meet at least quarterly and respond back to the Growing Area Classification Committee on its findings and recommendations.

Recommended that the ISSC pursue funding to facilitate scheduling a summit to bring together experts to present the current science in the use of MSC.

Action by 2013 Task Force I Recommended adoption of Growing Area Classification Committee action on Proposal 11-103.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force I on Proposal 11-103.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 11-103.

Action by 2015 Growing Area Classification Committee Recommended referral of Proposal 11-103 to appropriate committee as determined by the Conference Chair.

Action by 2015 Task Force I Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.

Action by 2015 General Assembly Adopted recommendation of Task Force I on Proposal 11-103.

Action by FDA January 11, 2016 Concurred with Conference action on Proposal 11-103.

Action by 2017 Growing Area Classification Committee Recommended adoption of Proposal 11-103 as amended.

Add a new section as follows:

Chapter XV. Depuration  
 .03 Other Model Ordinance requirements

K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD).

If the conditionally restricted growing area from which the shellstock is being depurated is impacted by wastewater treatment system discharge (generally that section of the conditionally restricted growing area located within the 300:1 to 1000:1 dilution lines), then supplemental requirements for depuration using MSC viral controls may be required. Depuration using MSC viral controls may be seasonally limited and may be species and depuration facility specific. Contaminant reduction studies as described in (1) below are recommended unless the SSCA and the Depuration Facility Operator have significant experience with the depuration process using MSC viral controls.

(1) Male-specific coliphage may be used in addition to fecal coliform for species-specific, growing area-specific, and depuration system-specific contaminant reduction studies. These contaminant reduction studies should demonstrate that:

(a) Predictable periods of time exist when male-specific coliphage levels are less than 1,000 PFU/100gm in shellfish meats,

(b) Male-specific coliphage and fecal coliform can be consistently reduced below end-point requirements, and

(c) Critical limits of season, process water temperature and salinity, and system design and operation limitations can be assessed and determined

(d) Species-specific operating protocols may be developed from the contaminant reduction studies for each conditionally restricted growing area that includes:

(i) Calendar dates when depuration shall be permitted,

(ii) Water temperature and salinity limitations,

(iii) Minimum processing time,

(iv) Sampling requirements and release criteria, and

(v) Operating Protocol.

(2) All requirements of Chapter XV shall be followed,

(3) A single 0-day MSC shellfish meat sample is required.

(4) The MSC end-point requirement for depuration is 50 PFU/100gm. If the single 0-day sample exceeds 50 PFU/100gm, then triplicate samples are required prior to release of product.

(5) The geometric mean of the triplicate samples used for product release must not exceed 50PFU/100gm and no single sample over 100 PFU/100gm.

(6) Extended depuration may be permitted to achieve end-point requirements.

(7) Evaluation of male-specific coliphage samples shall be performed in an NSSP conforming laboratory.

Action of 2017  
Task Force I

Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.