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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 Guide Reference: | NSSP Section II Model Ordinance Chapter IV Shellstock Growing Area @ .02 Bacteriological Standards G. – add new section (4) |
| Text of Proposal/ Requested Action | <u>(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.</u> |
| 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 (if available): | 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 | Recommended 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 | Recommended referral of Proposal 11-103 to an appropriate committee as determined by the Conference Chairman. |

Committee

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.