

Proposal Subject: Use of Analytical Methods Other than NSSP Methods

Specific NSSP Guide Reference: 2009 NSSP Section II Model Ordinance Chapter III Laboratory @ .02 Methods, Paragraphs A, C, D (1) and (2)

Text of Proposal/ Requested Action Revise Chapter III @.02 Methods, Paragraphs A, C and D as follows.
Chapter III @ .02 Methods

A. Microbiological. Methods for the analyses of shellfish and shellfish harvest waters shall be:

- (1) The methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and listed in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.
- (2) When there is an immediate need for a method of analysis and no NSSP approved analytical method exists, a validated AOAC, BAM or EPA method may be used.
- (3) When there is an ongoing critical need for a method of analysis and no NSSP approved analytical method exists an emergent method may be used pursuant to .02 D (1) and (2) below.

B. Chemical and Physical

- (1) Methods for the analysis
 - (a) Be the current
 - (b) Express results of all
- (2) When an AOAC.....
- (3) If a method is not

C. Biotoxin. Methods for the analyses of shellfish shall be:

- (1) The current AOAC and APHA
- (2) The current APHA method
- (3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and listed in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.
- (4) When there is an immediate need for a method of analysis and no NSSP approved method exists, a validated AOAC method may be used.
- (5) When there is an ongoing critical need for a method of analysis and no NSSP approved method exists, an emergent method may be used pursuant to .02 D (1) and (2) below.

D. Emerging Methods.

- (1) When there is an ongoing critical need for a method of analysis

and no NSSP approved method exists, the ISSC Executive Board may consider allowing an unapproved or non-validated method to be used for a specific purpose. The minimum requirements as defined in the Laboratory Methods Review Committee Advisory for Emerging Methods will be provided to the Executive Board and shall contain the following:

Name of Method;

Date of Submission;

Specific purpose or intent of the method for use in the NSSP;

Step by step procedure including equipment, reagents and safety requirements necessary to run the method;

Data generated in support of the efficacy of the method if available;

Any peer reviewed articles detailing the method and its efficacy;

Name of the developer(s) or SSCA submitter;

Developer/submitter contact information.

- (2) Within two years of the initial allowed use of the emerging method, the entire Single Lab Validation Protocol should be completed and submitted to the ISSC for consideration as an approved method. The Laboratory Methods Review Committee will review the submission and report to the Executive Board on its Status.

Public Health Significance:

Cost Information (if available): None

Action by 2011 Laboratory Methods Review Committee Recommended no action on Proposal 11-105. Rationale – Proposal 11-105 is addressed by action on Proposal 11-104.

Action by 2011 Task Force III Recommended no action on Proposal 11-105. Rationale-Proposal 11-105 was resolved by Task Force action on Proposal 11-104.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-105.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-105.